Supreme Court, U.S.
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No. 05-656

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,
Petitioner,

v.

CENTOCOR, INC., *et al.*,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Does the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a material breach of a license agreement by a licensee prior to suit for declaratory relief for patent infringement, invalidity, or unenforceability?

LIST OF PARTIES

Petitioner was the only appellant in the court below. Respondents are Centocor, Inc.; the Trustees of Columbia University in the City of New York; and the Board of Trustees of the Leland Stanford Junior University, all appellees in that court.

LIST PURSUANT TO RULE 29.6

Petitioner is a publicly held corporation. No publicly held entity owns 10% or more of its stock.

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Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

Petitioner prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Federal Circuit entered in this case June 1, 2005.

OPINIONS BELOW

The opinion of the United States District Court for the District of Maryland denying jurisdiction under Article III and the Declaratory Judgment Act is unreported and is reproduced in the Appendix at A. 33a.[1] The previous opinion of the same court upholding jurisdiction under Article III and the Declaratory Judgment Act is reported at 271 F. Supp. 2d 762 and is reproduced at A. 11a. The opinion of the United

[1] Citations to "A." are to the appendix to this petition. Citations to "C.A.A." are to the joint appendix filed in the Court of Appeals, and to "C." to the second amended complaint.

States Court of Appeals for the Federal Circuit is reported at 409 F.3d 1376 and is reproduced at A. 1a. Its order denying rehearing and rehearing *en banc* is unreported and is reproduced at A. 40a.

JURISDICTION

The judgment of the Court of Appeals was entered June 1, 2005. A timely petition for rehearing and rehearing *en banc* was denied August 25, 2005. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article III of the Constitution of the United States and 28 U.S.C. §§ 1331, 1338(a) and 2201(a) are reproduced at A. 41a.

STATEMENT

A. The Patent and License.

Petitioner, MedImmune, Inc., is a biotechnology company. It manufactures and markets the pediatric drug Synagis®, the only drug in the United States indicated for prevention of potentially fatal respiratory tract infections caused by respiratory syncytial virus in infants. Synagis® was approved by the United States Food and Drug administration on June 18, 1998, and petitioner began selling Synagis® in September of the same year. Synagis® has accounted for at least 80% of petitioner's sales since 1999.

Respondent universities own the rights to U.S. Patent No. 5,807,715 ("the '715 patent"), and respondent Centocor is their exclusive licensee.[2] A. 12a, 33a-34a; C.A.A. 60, 135.

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[2] Respondent Centocor is licensed by the owners of the patent—respondent trustees of Columbia and Stanford Universities—to make, use, and sell products pursuant to the '715 patent, and to sublicense and enforce it. A. 12a & n.3.

As characterized by respondents, the '715 patent claims a "pioneering technology" that relates to a "basic method" of producing antibody molecules used to help prevent disease. C.A.A. 137. Although the application that led to the '715 patent was filed in the U.S. Patent and Trademark Office ("PTO") August 27, 1984, the patent did not issue until September 15, 1998. C.A.A. 60.

Pursuant to PTO regulations, the '715 patent's claims and disclosures were kept confidential for the fourteen years between the filing of the application and the date of issue. During that time, petitioner was founded, engaged in years of research and discovery in developing Synagis®, obtained its own patents on Synagis® from the PTO and other patent authorities worldwide, and conducted the rigorous, lengthy and expensive preclinical and clinical trials necessary to launch Synagis®. During this entire period, petitioner was unaware of the pendency of the '715 patent application, which claimed "pioneering technology." C. 6, 7.

In May 1999 Centocor announced to petitioner that petitioner's Synagis® product was "covered by [*i.e.*, infringed] the '715 Patent." C. 7 (brackets in original). Petitioner in reply challenged that assertion. *Id.* At a meeting in March 2000, Centocor threatened petitioner and its distributor with a suit for infringement unless petitioner agreed to a license from Centocor. C. 7. Such litigation would have had a serious and immediate effect on petitioner. C. 8. Negotiations and more threats of litigation followed. C. 7-8. Finally in December 2000 petitioner and Centocor entered into a sublicense agreement, which required petitioner to pay royalties for "licensed product[s]," defined only as products falling within the scope of the claims of the '715 patent. A. 13a. The agreement did not name Synagis® as such a product, contained no acknowledgment of validity or infringement of the '715 patent, and included no agreement not

to litigate. Petitioner has paid royalties pursuant to that license since December 2000, and continues to do so.[3]

In March 2002 petitioner sent Centocor a letter recounting the circumstances under which petitioner had been economically compelled to enter the license, and stating again petitioner's conclusion that the '715 patent was invalid and did not cover Synagis®. C.A.A. 1122-23. Petitioner denied that it had any obligation to make royalty payments under the license. In a letter dated April 1, 2002, Centocor disputed petitioner's conclusions and stated that it required petitioner to continue to pay royalties under the license agreement. C. 9-10.

B. The Present Action.

Four days later petitioner filed this action against Centocor in the United States District Court for the District of Maryland, invoking the Declaratory Judgment Act, 28 U.S.C. § 2201, and seeking declarations that:

> (1) Synagis® is not a "licensed product" under the license agreement (*i.e.*, that Synagis® does not infringe the claims of the '715 patent);
>
> (2) the '715 patent is invalid and/or that Synagis® did not infringe the claims of the '715 patent; and
>
> (3) the '715 patent is unenforceable because of misconduct by respondents before the PTO, including misrepresentations and omissions concerning the enablement of the invention.

A. 13a.

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[3] Petitioner in order to market Synagis® also agreed to a license from Genentech, Inc., which asserted infringement of its own very broad patent claims allegedly covering production of monoclonal antibodies. Petitioner separately sought a declaratory judgment against Genentech; a petition for certiorari in that case is pending. *MedImmune, Inc.* v. *Genentech, Inc.*, No. 05-608.

Respondents thereupon filed their own declaratory judgment action in the United States District Court for the Northern District of California, alleging that "[a]n actual controversy exists." C.A.A. 140. A "mirror image" of petitioner's suit, A. 3a, 13a-14a, their complaint prayed for a declaration that petitioner by ceasing to pay royalties would be infringing the claims of the '715 patent, and that the claims of that patent were valid and enforceable. A. 14a n.4. The District Court in California dismissed respondents' complaint in favor of petitioner's first-filed and pending case in Maryland. A. 14a-15a.[4]

C. The District Court's First Decision.

The University respondents then moved to dismiss the Maryland action on the ground that, because of the existing license agreement between petitioner and Centocor, with which petitioner was complying, there was no justiciable controversy between the parties under Article III and the Declaratory Judgment Act. C.A.A. 636-37. The District Court denied the motion. A. 31a. Stating the issue as whether petitioner "must first breach the licensing agreement (e.g., stop paying royalties) before an actual controversy can arise," A. 17a, the court held that the "relevant case law on the issue does not demand" breach of the license agreement in order for an "actual controversy" to be present:

> "The Court finds that under the totality of the circumstances, there is a reasonable apprehension of an infringement suit (even in the absence of a breach of the licensing agreement) sufficient to create an 'actual controversy'. *Although the parties are under license, there is a clear and concrete dispute between them about whether Synagis® infringes on the '715 patent.* It is

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[4] *Centocor, Inc.* v. *MedImmune, Inc.*, No. C 02-3252, U.S. Dist. Ct., N.D. Cal. (Oct. 21, 2002). The dismissal was based also on the court's discretion, and on lack of an actual controversy because of the anticipated ruling of the court in Maryland. See A. 3a, 14a-15a, 19a n.7.

> beyond doubt that were MedImmune to breach the licensing agreement, Defendants would immediately file suit on infringement (and possibly other) grounds. . . . Under the circumstances in the present case, the Court finds that such a threat can exist in the absence of any breach of the licensing agreement."

A. 18a-19a (emphasis supplied).

The District Court pointed to the function of the Declaratory Judgment Act, and the established principle that breach of an agreement is not required prior to suit seeking a declaration of rights: "The purpose of these type of actions is to remove the harmful uncertainty that arises when a party is unsure as to its legal position." A. 19a n.6. The District Court reviewed Federal Circuit case law and found no support for the proposition that breach of a license agreement was required in order to meet the "actual controversy" requirement of the Declaratory Judgment Act. A. 18a. The District Court held that "[i]t is beyond doubt that were MedImmune to breach the licensing agreement, Defendants would immediately file suit on infringement (and possibly other) grounds." A. 19a.

D. The District Court's Second Decision.

However, in June 2004 the District Court on respondents' motion dismissed petitioner's declaratory judgment suit for lack of jurisdiction. A. 39a. The District Court explained that it was bound to overturn its prior ruling because of a decision of the Federal Circuit first announced three months earlier, *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 125 S. Ct. 351 (2004) (No. 04-260). A. 36a, 38a-39a. Under that decision, the Federal Circuit announced a rule that when a patent licensee had complied with, rather than violated, its royalty obligations, there could be no "actual controversy" within the meaning of the Declaratory Judgment Act and the requirements of Article

III of the Constitution. The District Court quoted and applied this new constitutional interpretation as set forth by the Federal Circuit in *Gen-Probe*:

> "[A] licensee must, at a minimum, stop paying royalties (and thereby materially breach the agreement) before bringing suit to challenge the validity or scope of the licensed patent."

A. 38a, quoting *Gen-Probe*, 359 F.3d at 1381. Concluding that the facts in petitioner's action were "identical in all material aspects" to those of *Gen-Probe*, A. 37a, the District Court dismissed the case. Petitioner appealed to the United States Court of Appeals for the Federal Circuit.

E. The Federal Circuit's Decision.

The Federal Circuit (Schall, J., joined by Bryson and Gajarsa, JJ.) affirmed the dismissal, holding that "the district court did not err in ruling that no Article III case or controversy existed," A. 10a, and that "*Gen-Probe* is determinative of this case," A. 5a.

Quoting its *Gen-Probe* decision, the Federal Circuit reiterated the rule announced there that a "license, 'unless materially breached, obliterated any reasonable apprehension of a lawsuit,'" and was excluded from federal jurisdiction under the Declaratory Judgment Act. A. 5a, quoting *Gen-Probe*, 359 F.3d at 1381. It added that "[q]uite simply, *once the license agreement was in place* and MedImmune was in compliance with the terms of the agreement, MedImmune *could not* be under a reasonable apprehension that it would face an infringement suit by Centocor." A. 5a-6a (emphasis supplied).

The Court of Appeals rejected petitioner's arguments that the *Gen-Probe* decision so read was inconsistent with this Court's decisions under Article III and the Declaratory Judgment Act, also with this Court's decisions in *Lear, Inc.* v.

Adkins, 395 U.S. 653 (1969), and *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83 (1993), as well as with the Federal Circuit's own prior decisions. A. 6a-8a.

The Court of Appeals further held that it made no difference in applying the "actual controversy" requirement that respondents had themselves even brought suit against petitioner. That had occurred, the Federal Circuit emphasized, "*after* MedImmune filed its declaratory judgment suit, A. 9a (emphasis in original), and "[l]ater events may not create jurisdiction where none existed at the time of filing," *id.*, quoting *GAF Bldg. Materials Corp.* v. *Elk Corp.*, 90 F.3d 479, 483 (Fed. Cir. 1996). "MedImmune," it held, because of compliance with the license, "could not be under a reasonable apprehension that it would face an infringement suit by Centocor." A. 6a.

Petitioner sought rehearing and rehearing *en banc*, arguing that "the panel decision conflicts with prior decisions of the Supreme Court and this Court."[5] The Court of Appeals denied the petition. A. 40a.

REASONS FOR GRANTING THE WRIT

This petition raises the same Article III and Declaratory Judgment Act issue that is pending before this Court in *MedImmune, Inc.* v. *Genentech, Inc.*, No. 05-608, and was, until withdrawn, previously presented to this Court in *Gen-Probe Inc.* v. *Vysis, Inc.*, No. 04-260.[6] The Federal Circuit's new *Gen-Probe* doctrine, applied in the present case once again, effectively eliminates declaratory actions by patent licensees against their licensors—in spite of this Court's holding in *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969), and

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[5] Petition for Rehearing En Banc, Fed. Cir., No. 04-1499, June 15, 2005, at 2.

[6] By agreement of the parties, the petition for certiorari in *Gen-Probe* was dismissed pursuant to this Court's Rule 46.1. 125 S. Ct. 351 (2004).

contrary to this Court's decisions applying the Declaratory Judgment Act and Article III going back to the 1930s.[7] The District Court, superseding its pre-*Gen-Probe* ruling, recognized that *Gen-Probe* was a revision of the Federal Circuit's law on Article III and the Declaratory Judgment Act as previously applied to patent challenges involving licenses. A. 37a-38a. This new rule of constitutional law now has been approved in four panel opinions, joined by seven of the Federal Circuit's twelve active judges and two of its senior judges. Rehearing *en banc* twice has been denied, both in *Gen-Probe* and now in the present case.[8]

Besides misinterpreting Article III and revising the Declaratory Judgment Act, the decision is contrary to the policy of the patent laws themselves as declared in this Court's decision in *Lear, Inc.* v. *Adkins*, which disallowed the doctrine of licensee estoppel. Because the Federal Circuit is the appellate court for patent claims, its new doctrine now governs essentially every patent licensee. See *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993)

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[7] The "actual controversy" requirement of the Declaratory Judgment Act extends to the limits of the "Cases" or "Controversies" jurisdiction of Article III. *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 239-40 (1937); *ACandS, Inc.* v. *Aetna Cas. & Surety Co.*, 666 F.2d 819, 822 (3d Cir. 1981).

[8] See, in addition to *Gen-Probe* and the present decision, *MedImmune, Inc.* v. *Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005), *pet'n for cert. pending* (No. 05-608); *Metabolite Labs., Inc.* v. *Laboratory Corp. of America Holdings*, 370 F.3d 1354, 1369 (Fed. Cir. 2004) (vacating judgment in part because "in light of LabCorp's continuing royalty payments on the panel test, LabCorp cannot itself challenge the validity of a claim for which it continues to pay royalties"), *cert. granted*, 74 U.S.L. WEEK 3287 (2005) (No. 04-607). See also, applying the Federal Circuit's interpretation of Article III outside the patent-license context, *Teva Pharmaceuticals USA, Inc.* v. *Pfizer, Inc.*, 395 F.3d 1324, *rehearing en banc denied*, 405 F.3d 990 (Fed. Cir.), *cert. denied*, 125 S. Ct. 1413 (2005) (No. 05-48).

(Federal Circuit patent doctrine "a matter of special importance to the entire Nation"). And because the *Gen-Probe* license cases rest on Article III and the Declaratory Judgment Act, and cannot logically be limited only to patent licenses, it affects basic federal law throughout the country.

I. THE FEDERAL CIRCUIT'S DECISION CONFLICTS WITH DECISIONS OF THIS COURT AND OF OTHER COURTS OF APPEALS.

A. The Decision Is Contrary to This Court's Holdings on Article III and the Declaratory Judgment Act.

In *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227 (1937), this Court in upholding the Declaratory Judgment Act, 28 U.S.C. § 2201(a), explained that

> "Where there is such a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged, the judicial function may be appropriately exercised although the adjudication of the rights of the litigants may not require the award of process or the payment of damages."

300 U.S. at 241. This Court held that a dispute over the meaning of terms of insurance policies presented "a dispute . . . manifestly susceptible of judicial determination." *Id.* at 242.

Soon after *Aetna* this Court specifically held that the Declaratory Judgment Act applied to a patent-license challenge. Pointing out the immediacy of the dispute, this Court explained that

> "certainly the requirements of case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary

> or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim."

Altvater v. *Freeman*, 319 U.S. 359, 365 (1943). Further, that opinion held:

> "It is said that so long as petitioners are paying royalties they are in no position to raise the issue of invalidity—the theory being that as licensees they are estopped to deny the validity of the patents and that, so long as they continue to pay royalties, there is only an academic, not a real controversy, between the parties. . . . *The fact that royalties were being paid did not make this a 'difference or dispute of a hypothetical or abstract character.'*"

Id. at 364 (emphasis supplied), quoting in part *Aetna*, 300 U.S. at 240.

Prior to the Federal Circuit's decision in *Gen-Probe*, the District Court here explicitly found that "Although the parties are under license, *there is a clear and concrete dispute* between them about whether Synagis® infringes on the '715 patent." A. 18a-19a (emphasis supplied). Those facts have not changed:

> —The '715 patent has issued from the PTO, and unless successfully challenged remains in force until its expiration in 2015.
>
> —The license agreement is in force for the duration of the '715 patent.
>
> —"Although the parties are under license, there is a clear and concrete dispute between them about whether Synagis® infringes on the '715 patent." A. 18a-19a.
>
> —The declaration of rights sought by petitioner will be definitive. If Synagis® is found to infringe the '715 patent and the patent is upheld, that determination will be binding on petitioner. If the '715 patent is declared

> invalid or unenforceable for misconduct, or not to cover Synagis®, that decision will be binding on respondents.

That an "actual controversy," 28 U.S.C. § 2201(a), exists here appears beyond any sensible dispute. Evidenced by its letters and actions prior to and including filing declaratory suit in 2002, petitioner actively disputes that it has an obligation to pay royalties on the '715 patent. Respondents conversely continue to claim that royalties are owed. Indeed, respondents even filed their own declaratory suit in another forum, alleging the same facts to be an "actual controversy." See pp. 4-5, *supra*. It is difficult to see how this long and contentious controversy, which the two sides have respectively attempted to put before two federal district courts, is not an "actual controversy" under 28 U.S.C. § 2201(a). As the District Court put it, "both sides have shown an eagerness to resolve the dispute between them." A. 19a.

The only thing that has changed since the District Court recognized the "clear and concrete dispute" between the parties, *id.*, is the Federal Circuit's application of constitutional law: the Federal Circuit's *Gen-Probe* decision, setting forth a new and arbitrary rule that a licensee must breach a license agreement prior to filing a declaratory action. The Declaratory Judgment Act certainly does not say that. All that it requires is an "actual controversy." 28 U.S.C. § 2201(a). Such a controversy is abundantly present here. Here, just as in *Aetna*,

> "There is here a dispute between parties who face each other in an adversary proceeding. The dispute relates to legal rights and obligations arising from the contracts . . . . The dispute is definite and concrete, not hypothetical and abstract. Prior to this suit, the parties had taken adverse positions with respect to their existing obligations. . . . It calls, not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts."

300 U.S. at 242.

In adopting an absolute requirement that bars declaratory judgment actions and permits no discretion when the licensee is in compliance with the contract, the Federal Circuit has misunderstood this Court's direction, reiterated in many cases, that there can be no absolute or "precise test for determining in every case whether there is such [an actual] controversy," and

> "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

Maryland Cas. Co. v. *Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941). Even before *Aetna*, in reviewing a state-court declaratory proceeding, this Court recognized that jurisdiction under Article III is not precluded "so long as the case retains the essentials of an adversary proceeding, involving a real, not a hypothetical, controversy, which is finally determined by the judgment below." *Nashville, C. & St. L. Ry.* v. *Wallace*, 288 U.S. 249, 264 (1933).

B. The Decision Is Contrary to Declaratory Judgments on Licenses and Other Contracts in Other Circuits.

The Federal Circuit's requirement that there be "reasonable apprehension of suit," A. 5a, *Gen-Probe*, 359 F.3d at 1380, which can be produced only by material breach of a license, has no grounding in precedent from other circuits or in the language of the statute. The words of the Declaratory Judgment Act are explicit in what it requires: simply an "actual controversy." 28 U.S.C. § 2201(a). Dozens of cases for dozens of years have recognized that an "actual controversy" can exist without importing an additional, non-statutory requirement for material breach and "apprehension of suit."

Under the Federal Circuit law applied here, for a patent licensee to bring a declaratory judgment action, "there must be both (1) a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity." A. 5a. And as *Gen-Probe* explicitly stated, it is impossible for any licensee not in breach to meet that test, because the "license, unless materially breached, obliterate[s] any reasonable apprehension of a lawsuit . . . ." *Gen-Probe*, 359 F.3d at 1381.[9]

The Federal Circuit has lost sight of the fact that the "reasonable apprehension" inquiry is only a proxy for the "actual controversy" standard, coextensive with Article III, that Congress enacted in the statute. Other circuits recognize that *Aetna* and the decisions following it establish that apprehension of a lawsuit

> "is not the only way to establish the existence of a case for purposes of Article III. The reasonable apprehension of suit doctrine exists to cabin declaratory judgment actions where the only controversy surrounds a potential, future lawsuit."

Sallen v. *Corinthians Licenciamentos LTDA*, 273 F.3d 14, 25 (1st Cir. 2001). Two Federal Circuit judges in dissent has pointed this out.[10]

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[9] The "reasonable apprehension" requirement in the Federal Circuit traces its origin to an era prior to *Lear*, when because of licensee estoppel patent licensees could not bring suit under any circumstances. See, *e.g.*, *C.R. Bard, Inc.* v. *Schwartz*, 716 F.2d 874, 879 (Fed. Cir. 1983), citing *Japan Gas Lighter Ass'n* v. *Ronson Corp.*, 257 F. Supp. 219 (D.N.J. 1966).

[10] See *Teva Pharmaceuticals USA, Inc.* v. *Pfizer Inc.*, 405 F.3d 990, 997 (Fed. Cir. 2005) (Dyk, J., dissenting from denial of rehearing *en banc*) ("In my view, the First Circuit is correct: the proper test under

The Second Circuit, in a frequently cited case, held in 1977 that

> "Addressing the question whether a patent licensee must actually withhold royalty payments before he can challenge validity, we conclude—as have most courts who have considered the issue—that such repudiation of the licensing agreement should not be precondition to suit."

Warner-Jenkinson Co. v. *Allied Chem. Corp.*, 567 F.2d 184, 187 (2d Cir. 1977) (citing cases). In another pre-Federal-Circuit case, the Seventh Circuit in *Precision Shooting Equip. Co.* v. *Allen*, 646 F.2d 313 (7th Cir.), *cert. denied*, 454 U.S. 964 (1981), considered whether "a valid license is an absolute defense to a patent infringement action, since Bear, as licensee, can have *no reasonable apprehension of liability in an infringement suit*." *Id.* at 314 (emphasis supplied). The court held that the license did not negate a justiciable Article III controversy, recognizing a "useful purpose" in "test[ing] out whether or not the patentee is entitled to the monopoly and royalties it claims or whether what it seeks to protect for itself is really part of the public domain," and noting that a decision on validity "will impact upon the business dealings between the parties." *Id.* at 318. The Seventh Circuit focused on whether the licensee alleged "a reasonable apprehension that the patentee will bring an infringement suit against him *if there is non-compliance with the license*." *Id.* (emphasis supplied). That test, rather than the absolute bar set here by the Federal Circuit, reflects the "actual controversy" standard prescribed by the Declaratory Judgment Act.

Under the regional circuits' understanding—inquiring under *Aetna* whether there is a controversy that is "definite and

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Article III is whether there is a present concrete controversy, and the panel here applied an incorrect test ['reasonable apprehension of suit'].").

concrete," "appropriate for judicial determination," and "not hypothetical or abstract," but "real and substantial," 300 U.S. at 240-42—it is clear that there is an "actual controversy" here. Petitioner is not a mere opportunist or interloper seeking to challenge the patent. Petitioner is party to a license, the terms of which are defined in part by the validity and scope of the '715 patent; petitioner seeks a declaration from the court as to the legal obligation to make payments under that license. As found by the District Court:

> "Although the parties are under license, there is a clear and concrete dispute between them whether Synagis® infringes on the '715 patent. It is *beyond doubt that were MedImmune to breach the licensing agreement, Defendants would immediately file suit on infringement (and possibly other) grounds.*"

A. 19a (emphasis supplied).

Petitioner under the Declaratory Judgment Act is not required to "sit back and continue to wonder if it is justly paying royalties or merely paying a bribe to the patentee not to threaten him with business disruption and a possible damage suit if he terminates royalty payments." *Precision Shooting*, 646 F.2d at 318. Nor should petitioner be "force[d] . . . to take some additional act to deepen gray into black and to expand the potential of litigation resulting in further business disruption while we pretend in the meantime that there is no actual controversy." *Id.* at 318-19.

For parties in a contractual relationship, the Declaratory Judgment Act authorizes federal courts to resolve "actual controversies" concerning the parties' respective rights, even when there has been no breach, and even when because of compliance under protest there is no apprehension of suit. A federal court's jurisdiction under the Declaratory Judgment Act with respect to licensed patents is just as broad as its

jurisdiction to declare the rights of parties to any other contract. See *Aetna*, 300 U.S. at 240. The Federal Circuit, however, appears to believe that a special and narrower Article III applies to patent licensees. In *Gen-Probe*, attempting to distinguish this Court's *Aetna* decision, it suggested that

> "While this language suggests that a litigant may sue to determine contract rights before a breach, this 1937 Supreme Court case did not involve a declaratory judgment action instituted by a patent licensee in good standing."

359 F.3d at 1382. But "this 1937 Supreme Court case" states a fundamental constitutionally-based rule of general application. There is no special rule for patent-license cases that limits a federal court's jurisdiction under Article III.[11]

The Federal Circuit's *Gen-Probe* line of cases cannot be reconciled with the law applied to licensees of intellectual property in other circuits. See, *e.g.*, *Hal Roach Studios, Inc.* v. *Richard Feiner & Co.*, 896 F.2d 1542, 1556 n.23 (9th Cir. 1990) (copyright license); *Société de Conditionnement* v. *Hunter Engineering Co.*, 655 F.2d 938, 943-44 (9th Cir. 1981) (patent license; case antedating Federal Circuit). Nor is it compatible with federal law on declaratory actions involving licenses and other contracts generally. *E.g.*, *Keener Oil & Gas Co.* v. *Consolidated Gas Utilities Corp.*, 190 F.2d 985, 989 (10th Cir. 1951) ("a party to a contract is not compelled to wait until he has committed an act which the other party asserts will constitute a breach, but may seek relief by declaratory judgment and have the controversy adjudicated in order that he may avoid the risk of damages or other untoward consequence"); *American Machine & Metals*,

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[11] The Federal Trade Commission has criticized "reasonable apprehension of suit" as an improperly narrow test for the existence of an Article III "Controversy." See Brief of *Amicus Curiae* Federal Trade Commission at 14-18, *Teva Pharmaceuticals USA, Inc.* v. *Pfizer, Inc.*, No. 04-1186, U.S. Ct. Apps., Fed. Cir. (Mar. 31, 2004).

Inc. v. *De Bothezat Impeller Co.*, 166 F.2d 535, 536 (2d Cir. 1948) ("The very purpose of the declaratory judgment procedure is to prevent the accrual of . . . avoidable damages.") See generally Petition for Certiorari, *MedImmune, Inc.* v. *Genentech, Inc.*, No. 05-608, at 13-16.[12]

II. THE *GEN-PROBE* DOCTRINE IS IRRECONCILABLE WITH *LEAR, INC.* v. *ADKINS*.

In *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969), this Court rejected the doctrine of "licensee estoppel" as "inconsistent with the aims of federal patent policy." 395 U.S. at 673. There is an

> "important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain. Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification."

Id. at 670. The statutory objective is "to encourage the prompt adjudication of patent validity." *Nebraska Engineering Corp.* v. *Shivvers*, 557 F.2d 1257, 1259 (8th Cir. 1977), quoting in part *Atlas Chem. Industries, Inc.* v. *Moraine Prods.*, 509 F.2d 1, 6 (6th Cir. 1974). "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly . . . ." *Pope*

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[12] See also, *e.g.*, *Venator Group Specialty, Inc.* v. *Matthew/Muniot Family, LLC*, 322 F.3d 835, 840 (5th Cir. 2003); *NUCOR Corp.* v. *Aceros y Maquilas de Occidente, S.A.*, 28 F.3d 572, 577 (7th Cir. 1994); *Continental Cas. Co.* v. *Coastal Sav. Bank*, 977 F.2d 734, 738 (2d Cir. 1992); *National Car Rental System, Inc.* v. *Computer Assocs. Int'l, Inc.*, 991 F.2d 426, 427-28 (8th Cir.), *cert. denied*, 510 U.S. 861 (1993); *S.O.S., Inc.* v. *Payday, Inc.*, 886 F.2d 1081, 1083 (9th Cir. 1989).

Mfg. Co. v. *Gormully*, 144 U.S. 224, 234 (1892), quoted in *United States* v. *Glaxo Group Ltd.*, 410 U.S. 52, 58 (1973). In *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993), this Court again emphasized "the importance to the public at large of resolving questions of patent validity."

Yet in the Federal Circuit, *Lear* has been under attack for years. In *Diamond Scientific Co.* v. *Ambico, Inc.*, 848 F.2d 1220 (Fed. Cir.), *pet'n for cert. dismissed*, 487 U.S. 1265 (1988), the Federal Circuit ruled—notwithstanding the policy enacted in the patent laws as recognized in *Lear*—that "there are still circumstances in which the equities of the contractual relationships between the parties should deprive one party . . . of the right to bring that challenge." 848 F.2d at 1224-25. In 1997 the Federal Circuit characterized this Court's holding in *Lear* as sounding "tones that echo from a past era of skepticism over intellectual property principles." *Studiengesellschaft Kohle, m.b.H.* v. *Shell Oil Co.*, 112 F.3d 1561, 1567 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 996 (1997). Finally in 2004 came *Gen-Probe*, and in 2005 this case, using Article III effectively to eliminate *Lear* from the Federal Circuit—the circuit where it must apply if anywhere.[13]

In spite of this Court's admonitions that "competition should not be repressed by worthless patents," *Pope, supra; Glaxo Group, supra*, the Federal Circuit has adopted a policy exactly opposite to Lear—citing as authority its own conclusion that challenges like petitioner's would produce "undesirable results." *Gen-Probe*, 359 F.3d at 1382. The Court of Appeals was persuaded that "[a]llowing this action to proceed would effectively defeat those contractual covenants and discourage patentees from granting licenses." *Id.* But this Court in *Lear* decided otherwise, holding that "contract

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[13] In *Gen-Probe* the Federal Circuit, listing several of its cases, acknowledged that "[i]n several instances, this court has declined to apply the *Lear* doctrine." 359 F.3d at 1381.

doctrine must give way before the demands of the public interest," 395 U.S. at 670, and warning that disallowing licensee challenges to patent validity would have an effect "particularly severe in the many scientific fields in which invention is proceeding at a rapid rate," *id.* at 673.

III. THE FEDERAL CIRCUIT'S *GEN-PROBE* DOCTRINE HAS BOTH LEGAL AND PRACTICAL IMPACT.

The Federal Circuit's decision here, like its others applying *Gen-Probe*, misconstrues not only federal patent policy but Article III itself. Contract disputes, of which patent licenses are just one subset, were a primary focus of Congress when it enacted the Declaratory Judgment Act in 1934. Congress explained its purpose to

> "enable[] parties in disputes over their rights over a contract, deed, lease, will, or any other written instrument to sue for a declaration of rights, *without breach of the contract* . . . ."

S. Rep. No. 1005, 73d Cong., 2d Sess. 2 (1934) (emphasis supplied). After the Declaratory Judgment Act, "it is not necessary to bring about such social and economic waste and destruction in order to obtain a determination of one's rights." *Id.* The Act was addressed to the very situation presented here: to allow a party to litigate "without the necessity for prior breach" of a contract, "risking disaster by acting on [its] own assumption or . . . not acting because of fear of consequences." E. BORCHARD, DECLARATORY JUDGMENTS 931-32 (2d ed. 1941); see also, *e.g.*, 10B C. WRIGHT, *et al.*, FEDERAL PRACTICE & PROCEDURE 457-58 (3d ed. 1998). The law in the Federal Circuit now has become just the opposite: a contracting party to a license agreement "must . . . materially breach the agreement . . . before bringing suit."

Gen-Probe, 359 F.3d at 1381. The district courts throughout the country in patent cases now as here, are applying that new law.[14]

A holding more contradictory to this Court's long-established construction and constitutional endorsement of the Declaratory Judgment Act can scarcely be imagined. And the Federal Circuit, whatever its presumed technical competence in purely patent issues, has no special expertise in construing Article III of the Constitution or the Declaratory Judgment Act. It is an occasional task of this Court to ensure that when applying basic federal statutes and constitutional provisions—enactments that apply in all circuits—the Federal Circuit does not wander into misinterpretations that contradict the holdings of the regional courts of appeals and of this Court.

This case is yet another example of a large firm[15] in the fast-developing biotechnology industry securing a broadly worded patent with sweeping claims, then through threats of perilous infringement litigation forcing many smaller or start-up companies to pay it royalties on those dubious claims, or else risk being put out of business. The Federal Circuit holds that without first betting the company by committing breach of contract and potential patent infringement, such an unfortunate licensee has no way to determine whether "it is justly paying royalties or merely paying a bribe." *Precision*

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[14] See, in addition to the District Court's reversal of its prior ruling in the present case, and the district court's reluctant adherence to *Gen-Probe* in *MedImmune, Inc.* v. *Genentech, Inc., supra*: *E.I. du Pont de Nemours & Co.* v. *Great Lakes Chem. Corp.*, 383 F. Supp. 2d 642 (D. Del. 2005) (applying *Gen-Probe* and dismissing declaratory judgment suit by licensee); *In re Columbia Univ. Patent Litig.*, 343 F. Supp. 2d 35, 49 (D. Mass. 2004) (citing *Gen-Probe*: "If Biogen Idec MA and Genzyme pay the annual license fee, any possible case or controversy may be extinguished.").

[15] Centocor is a wholly-owned subsidiary of Johnson & Johnson.

Shooting, 646 F.2d at 318. Only this Court can return the Federal Circuit to the correct meaning of Article III and the Declaratory Judgment Act, and restore the balance enacted by Congress in the patent laws.

CONCLUSION

For the reasons stated, certiorari should be granted and the case set for argument with No. 05-608, *MedImmune, Inc.* v. *Genentech, Inc.* Alternatively, the petition should be held for consideration following No. 05-608.

Respectfully submitted,

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November 22, 2005

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APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

04-1499

MEDIMMUNE, INC.,
Plaintiff-Appellant,

v.

CENTOCOR, INC.,
Defendant-Appellee,

and

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,
Defendants-Appellees.

DECIDED: June 1, 2005

Before SCHALL, BRYSON, and GAJARSA, *Circuit Judges.*

SCHALL, *Circuit Judge.*

MedImmune, Inc. ("MedImmune") appeals from the final decision of the United States District Court for the District of Maryland that dismissed, for lack of subject matter jurisdiction, MedImmune's declaratory judgment action against Centocor, Inc. ("Centocor"), the trustees of Columbia University in New York City, and the Board of Trustees of the Leland Stanford Junior University in California. In its suit, MedImmune sought to have U.S. Patent No. 5,807,715 ("the '715 patent") declared invalid and/or unenforceable. The court dismissed the action after it determined that Med-

Immune had failed to establish that an actual controversy existed between it and Centocor, as required under the Declaratory Judgment Act, 28 U.S.C. § 2201(a). *MedImmune, Inc. v. Centocor, Inc.*, No. AW-02-1135 (D. Md. June 17, 2004). We affirm.

BACKGROUND

I.

The '715 patent is titled "Methods and Transformed Mammalian Lymphocytic Cells for Producing Functional Antigen-Binding Protein Including Chimeric Immunoglobulin and Fragments." Columbia University and Leland Stanford Junior University are the assignees of the '715 patent. Centocor is the exclusive licensee of the patent, with the right to sublicense the patent to others.

The '715 patent issued in September of 1998. In a May 1999 letter, Centocor offered MedImmune a sublicense under the patent to cover MedImmune's Synagis® product. In August of 1999, MedImmune responded to Centocor's letter. In its response, MedImmune stated that it did not agree that Synagis® was covered by the '715 patent, and it indicated that it would not take a license.

In May of 2000, representatives from Centocor and MedImmune began license negotiations. The negotiations spanned several months. In these negotiations, MedImmune took the position that Synagis® did not infringe the '715 patent, that the patent was invalid and, alternatively, that MedImmune could design around the '715 patent. MedImmune claims that "facing mounting pressure and fearing an imminent infringement suit," it finally concluded a sublicense agreement with Centocor. The agreement was executed on December 29, 2000. Thereafter, MedImmune began paying royalties on Synagis® under the agreement. It is undisputed that MedImmune continues to make timely royalty payments and is not otherwise in breach of the license agreement.

After concluding the license agreement, MedImmune asserted to Centocor that it did not infringe the '715 patent and that the patent was invalid and/or unenforceable. In response, Centocor told MedImmune that it expected MedImmune to continue to adhere to its license obligations.

II.

In April of 2002, MedImmune filed the present declaratory judgment suit in the District of Maryland, seeking a declaration that it owes no royalties under the license agreement with Centocor and that the '715 patent is invalid and/or unenforceable. Shortly thereafter, Centocor and the universities filed what they characterize as a "mirror-image" declaratory judgment suit against MedImmune in the Northern District of California. In their suit, Centocor and the universities alleged that, in view of MedImmune's suit in Maryland, a case or controversy existed between them and MedImmune. They sought a declaratory judgment that the '715 patent is valid and enforceable, and that MedImmune's manufacture and sale of Synagis® infringes the patent.

The Maryland district court granted Centocor and the universities' motion to dismiss for lack of jurisdiction. Relying on *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), the court determined that MedImmune had failed to establish that an actual controversy existed between it and Centocor, as required under 28 U.S.C. § 2201(a). Centocor and the universities' suit in the Northern District of California was also dismissed, on the ground that there was "no actual controversy to satisfy the Declaratory Judgment Act" in light of the Maryland suit.

MedImmune timely appeals the decision of the Maryland district court dismissing its suit. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

ANALYSIS

I.

Whether an actual case or controversy exists so that a district court may entertain an action for a declaratory judgment of non-infringement and/or invalidity is governed by Federal Circuit law. *Minn. Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 672 (Fed. Cir. 1991); *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 954 n.3 (Fed. Cir. 1987). The determination of whether an actual controversy exists under the Declaratory Judgment Act in a patent case is a question of law that we review de novo. *Vanguard Research, Inc. v. PEAT, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002).

The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction . . . [a court] may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). Paralleling Article III of the Constitution, the Act "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1331 (Fed. Cir. 2005) (quoting *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996)). "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941).

To keep watch over the subtle line between an "abstract question" and "a controversy contemplated by the Declaratory Judgment Act," *id.*, an inquiry has been formulated that focuses on the conduct of both the patentee and the accused

infringer. When a potential infringer seeks declaratory relief in the absence of a lawsuit by the patentee, there must be both (1) a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity. *Teva*, 395 F.3d at 1330; *Gen-Probe*, 359 F.3d at 1380; *EMC Corp.*, 89 F.3d at 811.

II.

As noted above, the district court relied on our decision in *Gen-Probe* to dismiss MedImmune's declaratory judgment suit for lack of Article III jurisdiction. In *Gen-Probe*, we considered the case of a licensee in good standing who sought a declaratory judgment that it was not infringing the licensed patent, and that the licensed patent was invalid. 359 F.3d at 1377. The licensee sought a declaratory judgment while timely paying royalties and remaining faithful to the license agreement in all other respects. *Id.* at 1380.

In holding that there was no actual case or controversy for purposes of the Declaratory Judgment Act, we determined that the license, "unless materially breached, obliterated any reasonable apprehension of a lawsuit," and that once the licensor and licensee "formed the license, an enforceable covenant not to sue, the events that led to the formation [of the license] became irrelevant." *Id.* at 1381.

We agree with the district court that *Gen-Probe* is determinative of this case. Any controversy that may have existed between MedImmune and Centocor prior to and during their various negotiations vanished when MedImmune executed the license agreement, which is a covenant by Centocor not to sue. Quite simply, once the license agreement was in place and MedImmune was in compliance with the terms of the

agreement, MedImmune could not be under a reasonable apprehension that it would face an infringement suit by Centocor.[1]

III.

MedImmune does not seriously dispute that *Gen-Probe* is virtually on "all fours" with this case. Rather, it contends that we should not follow *Gen-Probe*. MedImmune argues that *Gen-Probe* is inconsistent with Supreme Court precedent and with prior Federal Circuit precedent. Consequently, it urges that, as a panel, we are not obligated to follow it. *See Atl. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 839 n.2 (Fed. Cir. 1992) (positing that "[a] decision that fails to consider Supreme Court precedent does not control if the court determines that the prior panel would have reached a different conclusion if it had considered controlling precedent"); *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988) ("Where there is direct conflict" between two Federal Circuit panel decisions, "the precedential decision is the first."). We do not agree with MedImmune that *Gen-Probe* is inconsistent with controlling Supreme Court and Federal Circuit authority.

First, MedImmune argues that *Gen-Probe* is fatally flawed because it failed to recognize the decision of the Supreme Court in *Cardinal Chemical Co. v. Morton International*, 508 U.S. 83 (1993). We think, however, that *Gen-Probe*'s failure to mention *Cardinal Chemical* reflects the fact that *Cardinal Chemical* was inapposite to *Gen-Probe*, rather than oversight

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[1] MedImmune argues that the license agreement contemplated that it could institute a declaratory judgment action of invalidity and/or unenforceability with respect to the '715 patent. This is so, MedImmune asserts, because "the sublicense agreement contained . . . no agreement not to litigate." (Br. of Appellant at 22.) This assertion overlooks the fact that a license is, by its nature, an agreement not to litigate. A licensor agrees to receive royalties or other consideration from the licensee in exchange for a covenant not to sue or disturb the licensee's activities.

on the part of the *Gen-Probe* court. The Supreme Court stated in *Cardinal Chemical* that its decision did not concern the jurisdiction of federal district courts:

> Under its current practice, the Federal Circuit uniformly declares that the issue of patent validity is "moot" if it affirms the District Court's finding of noninfringement and if, as in the usual case, the dispute between the parties does not extend beyond the patentee's particular claim of infringement. *That practice and the issue before us therefore concern the jurisdiction of an intermediate appellate court—not the jurisdiction of either a trial court or this Court.*

Id. at 95 (emphasis added). Consistent with the Court's statement of the limited issue before it in *Cardinal Chemical*, we have twice rejected the idea that *Cardinal Chemical* was meant to alter how a federal trial court determines whether a case or controversy exists over a declaratory judgment suit. *See Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995) (*Cardinal Chemical* "does not revolutionize the justiciability of declaratory judgment actions attacking a patent's validity. . . and nothing in *Cardinal* undermines our decisions on declaratory justiciability at the trial court level"); *Lamb-Weston Inc. v. McCain Foods, Ltd.*, 78 F.3d 540, 545 (Fed. Cir. 1996) ("The Supreme Court's decision in *Cardinal Chemical* is limited to the specific facts of that case.").

MedImmune also argues that *Gen-Probe* is inconsistent with the Supreme Court's rejection of the doctrine of licensee estoppel in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). This argument was addressed and rejected in *Gen-Probe*, 359 F.3d at 1381, and we likewise reject it here. Although *Lear* held that a licensee is not estopped from challenging the validity of a licensed patent, 395 U.S. at 670-71, "*Lear* . . . left unresolved the question when a federal court has jurisdiction of a licensee's claim of patent invalidity." *C.R. Bard, Inc. v.*

Schwartz, 716 F.2d 874, 878 (Fed. Cir. 1983). In other words, the fact that a party is not estopped from making an argument does not mean that federal courts have jurisdiction to entertain that argument in all circumstances.

Second, MedImmune urges that *Gen-Probe* is at odds with three decisions of this court: *C.R. Bard, Cordis Corp. v. Medtronic, Inc.*, 780 F.2d 991 (Fed. Cir. 1985), and *Intermedics Infusaid. Inc. v. Regents of the University of Minnesota*, 804 F.2d 129, 133 (Fed. Cir. 1986). We do not agree.

C.R. Bard noted that complete termination of the license may not be required for a licensee to sustain a declaratory judgment suit. 716 F.2d at 880. It does not follow from that proposition, however, that all licensees in good standing can challenge the validity of the licensed patent at their discretion, without regard to whether an actual controversy exists with the licensor.

Specifically, in determining that there was a case or controversy supporting jurisdiction over a licensee's declaratory judgment suit for, among other things, invalidity of the licensed patent, the *C.R. Bard* court found two facts to be important. First, the licensee had ceased paying royalties. Although this fact did not itself terminate the license, it constituted "a material breach of the agreement that, under the very terms of the agreement, enabled [the licensor] to terminate the agreement." *Id.* at 881. Second, the licensor had shown a willingness to enforce its rights by filing a state court action to recover the royalty payments. *Id.* at 881. This court then applied the "reasonable apprehension" test to these facts, determining that the licensee had a reasonable apprehension of suit. *Id.*

By contrast, in this case MedImmune can have no reasonable apprehension of suit—indeed, it can have no apprehension of suit at all—because there is nothing for which Centocor can sue MedImmune. It is undisputed that Med-

Immune continues to pay timely royalties for Synagis® and is not otherwise in breach of the agreement. The fact that Centocor *did* sue MedImmune, *after* MedImmune filed its declaratory judgment suit, does not alter the analysis. The presence or absence of a case or controversy is based on facts at the time the complaint was filed. *See. e.g., GAF Bldg. Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 483 (Fed. Cir. 1996) ("Later events may not create jurisdiction where none existed at the time of filing. Rather, the presence or absence of jurisdiction must be determined on the facts existing at the time the complaint under consideration was filed." (citations omitted)).

MedImmune's reliance on *Cordis* also is misplaced. *Cordis* did not address the question of whether there is a case or controversy sufficient to support subject matter jurisdiction over a licensee's suit for a declaratory judgment of patent invalidity where the licensee is not in breach of the license agreement. *See generally* 780 F.2d at 993-95. In *Cordis*, the licensee sought a declaration that the licensed patent was invalid. *Id.* at 993. However, the licensee also sought to pay royalties into escrow *pendente lite*, and to enjoin the licensor from canceling th license agreement. *Id.* It was these latter two requests, granted by the district court, that were before this court on appeal. *See id.*[2]

MedImmune points to *Intermedics* for the proposition that when a licensee wishes to maintain its license, it must continue to pay royalties to the licensor. *See* 804 F.2d 129, 133 (citing *Cordis*). That proposition, however, does not explain how there could be a case or controversy where, as here, the licensee is fully paying royalties directly to the licensor and is maintaining the license.

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[2] These issues were before the court based upon 28 U.S.C. §§ 1292(a) & (c), which confer jurisdiction upon this court to hear appeals from orders granting injunctions.

IV.

Finally, MedImmune urges us—assuming we conclude that we are bound by *Gen-Probe*—to recommend to the full court that it act en banc to overrule that decision. Although a three-judge panel of this court may not overrule a precedential decision of a previous panel, *see, e.g., Tate Access Floors, Inc. v. Interface Architectual Res., Inc.*, 279 F.3d 1357, 1366 (Fed. Cir. 2002), it may recommend en banc review of the decision. *See* Federal Circuit Rule 35(a)(2)(2004). We decline to do that in this case. Most importantly, as we have just explained, *Gen-Probe* is consistent with both Supreme Court precedent and with prior precedent of this court.

Beyond that, we reject MedImmune's argument that *Gen-Probe* should be overruled because it creates a "Hobson's choice." Specifically, MedImmune argues that it must "choose between paying tribute to a suspect patent and tying its fate to the uncertainty of patent litigation," with all of the attendant risks of such litigation. (Reply Br. of Appellant, at 2.) MedImmune's argument proves too much. Every potential infringer who is threatened with suit, or who is sued, for patent infringement must decide whether to settle or fight. In short, the "Hobson's choice" about which MedImmune complains arises not from *Gen-Probe*, but from Article III's requirement that, before a district court exercises jurisdiction in a declaratory judgment suit, there must be an actual controversy between the parties. For the reasons set forth above, such a controversy does not exist here.

CONCLUSION

Because the district court did not err in ruling that no Article III case or controversy existed to support MedImmune's declaratory judgment suit, it properly dismissed the suit for lack of jurisdiction. Therefore, the judgment of the district court is

AFFIRMED.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

Civil Action No. AW-02-1135

MEDIMMUNE, INC.,

Plaintiff,

vs.

CENTOCOR, INC., *et al.*,

Defendant.

MEMORANDUM OPINION

Currently pending before the Court in this declaratory judgment action brought by MedImmune, Inc. ("Plaintiff") against Centocor, Inc. ("Centocor") and the Board of Trustees of Leland Stanford Junior University and Columbia University ("Universities") (collectively, "Defendants") are the following pending motions: (1) the motion to dismiss for lack of subject matter jurisdiction filed by the Universities [116]; (2) the motion to dismiss for failure to plead with sufficient particularity filed by the Universities [63,64]; and (3) the motion to determine the party bearing the burden of proof filed by MedImmune [59].[1] The parties have also come before the Court for resolution of a lingering dispute regarding the provisions of the protective order that will govern

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[1] MedImmune also filed a Motion to File Surreply on the motion to dismiss for failure to plead with particularity [114]. Because the Court is ready to resolve the issue raised over the specificity in the Amended Complaint, the Court will DENY that motion as moot.

discovery in the case.[2] The motions have been fully briefed. On July 10, 2003, the Court held a motions hearing at which time each side was afforded the opportunity to present argument on the motions. Upon consideration of the arguments made in support of, and opposition to, the motions, the Court makes the following determinations.

I. *FACTUAL AND PROCEDURAL BACKGROUND*

The following is a summary of the facts necessary for adjudication of the pending motions. At the heart of this controversy is a patent which purports to cover "methods for producing functional immunoglobulin" and relates to the use of genetically altered cells to generate antibody molecules in the laboratory. The inventors ("Applicants") applied to the United States Patent and Trademark Office ("PTO") on August 27, 1984. The PTO issued the Patent ("'715 patent") fourteen years later in 1998. The '715 patent has been assigned to the Universities. Prior to the issuance of the patent on November 10, 1992, Centocor obtained an exclusive license to the patent through an agreement with the Universities.[3]

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[2] Although no formal motion has ever been filed regarding the protective order dispute, the parties have remitted to the Court numerous pleadings in which they propounded their arguments on the question of the wording of the protective order [61, 66, 72, 94, 96, 98].

[3] In the agreement between Centocor and the Universities, the Universities granted a "world-wide" license to Centocor to make, use and sell Licensed Products (which are defined as any Licensed Patent Products or Licensed Non-Patent Products). The Universities reserved the right to use the Patent for not-for-profit research purposes. They also reserved the right to grant non-exclusive sublicenses to four companies with which they were negotiating such agreements, and they reserved the right to bring legal action against any alleged infringer. Among other rights granted to Centocor in the Agreement was the right, upon notice to the Universities, to sue any alleged infringer, subject to the Universities right to bring suit within three months of the notice. Centocor agreed to seek sublicenses with third parties. Centocor's right to sublicense was subject to this restriction: "Any proposed sublicense shall be

In the years preceding the issuance of the patent, and prior to Plaintiff's awareness of it, Plaintiff was developing a drug called Synagis® which was approved by the Food and Drug Administration ("FDA") on June 18, 1998. Synagis® is a humanized monoclonal antibody that "targets a particular virus or source of disease." These monoclonal antibodies are artificially synthesized using recombinant DNA technology. Plaintiff began selling Synagis® in September 1998, after which it became one of Plaintiff's most important and successful pediatric drugs.

On May 19,1999, Centocor contacted Plaintiff to inform it that Synagis® was infringing on the '715 patent. Plaintiff disagreed that Synagis® infringed on the patent but was concerned about the allegation. Plaintiff responded to Defendant by claiming that Synagis® did not infringe on the patent. After lengthy negotiations, Plaintiff eventually agreed to enter into a Sublicense Agreement ("agreement" or "license") with Defendant in which it agreed to pay royalties to Defendant. After the formation of the agreement, Plaintiff claims, *inter alia*, that it came upon information which demonstrated that the patent was invalid and unenforceable because of, among other reasons, "inequitable conduct" by the Applicants during the patent application process before the PTO.

MedImmune filed the present declaratory judgment action in which in three counts it sought: (1) a declaration that MedImmune no longer owed royalties to Centocor because Synagis® was not a "licensed product" under the agreement, *i.e.*, absent the license it would not infringe on the patent held by Centocor; (2) a declaration that the patent was invalid and/or that Synagis® did not infringe on any valid patent; and (3) a declaration that the patent was unenforceable due to inequitable conduct. Defendants proceeded to file a mirror-

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subject to the prior written approval of Columbia, which approval shall not be unreasonably withheld." Agreement §§ 2,3.1,5.1, 12,13.4, 13.5(d).

image suit in the Northern District of California.[4] Both parties, in both actions, filed motions to dismiss and/or to transfer. In this action, Centocor argued that the case should be dismissed because MedImmune failed to join the Universities, who were, according to Centocor, necessary and indispensable parties to the action. MedImmune moved to dismiss the California action based on the "actual controversy" requirement and on the "first-to-file" rule.

Because both parties have cited to the decision of Judge Breyer, and because the Universities have tended to misstate his holding, the Court feels compelled to recite his ruling in some detail. *See Centocor, Inc. v. MedImmune, Inc.*, 2002 U.S. Dist. LEXIS 21109 (N.D.Cal. 2002). The Court in California dismissed the action for the following three reasons. First, the Court held that there was no "actual controversy" between the parties as required by statute. The Universities have misstated the rationale that the Court used in finding there to be no "actual controversy". The Court did hold that there was no "reasonable apprehension" of suit. It did not do so, however, because of the license between the parties. Rather, the Court found that the likelihood of an infringement suit was low because of the Maryland action:

> Here, future infringement is not only uncertain but unlikely. Should the Maryland court rule in favor of MedImmune and declare that the '715 patent is invalid, MedImmune would be free to stop its royalty payments to Centocor because there would be no patent to infringe. Should the court rule in favor of Centocor, there is no indication that MedImmune would discontinue performance of its obligations under the sublicense and

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[4] The complaint in the California action sought declarations that: (1) MedImmune infringes valid and enforceable claims of the '715 patent; (2) the claims of the '715 patent are valid; and (3) the claims of the '715 patent are enforceable.

> thus infringe the patent. In short, there is no immediate and real threat of infringement to justify declaratory relief at this time.

Id. at *8-9. Second, the Court held that even if there was an "actual controversy", it would exercise its discretion to decline jurisdiction, finding that a second case between the same parties would serve no purpose. Third, the Court held the "first-to-file" rule applicable.

By Order and Opinion dated December 12, 2002, this Court denied Centocor's motion to dismiss, but ordered that the Universities be joined as necessary parties. The Court found that because the Universities retain certain rights in the patent, they were indeed necessary parties. The Court also held, however, that if the Universities for some reason could not be joined, the action would proceed because the Universities were not indispensable. MedImmune thereafter filed an Amended Complaint, naming the Universities as defendants.

II. *SUBJECT MATTER JURISDICTION*

The Universities argue that the Court lacks subject matter jurisdiction over all the counts in the Amended Complaint. First, the Universities assert that the Court lacks subject matter jurisdiction over Count I because, although it is couched as a declaratory judgment claim, there is no "arising under" jurisdiction since only state law issues are presented by the claim. Second, the Universities argue that there is no "actual controversy" between the parties as to Counts II and III. MedImmune responds that Count I creates "arising under" jurisdiction because its resolution depends substantially on federal patent law and that Counts II and III present an actual "case or controversy" for judicial resolution. Finding subject matter jurisdiction over all claims, the motion will be denied.

A) *"Arising Under" Jurisdiction*

"The Declaratory Judgment Act, 28 U.S.C. § 2201, is 'remedial only, and is not itself a basis for federal subject

matter jurisdiction.'" *Volvo GM Heavy Truck Corp. v. United States DOL*, 118 F.3d 205,210 (4th Cir. 1997) (quoting *City Nat'I Bank v. Edmisten*, 681 F.2d 942, 945, n.6 (4th Cir. 1982)). Therefore, in order to sustain jurisdiction over a declaratory judgment claim, the party asserting jurisdiction must come forward with an independent basis—i.e., diversity or federal question—for the Court's jurisdiction. The initial burden of establishing jurisdiction lies with the party asserting it. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98, 124 L. Ed. 2d 1, 113 S. Ct. 1967 (1993).

In a declaratory judgment action, in order to make the jurisdictional determination, the Court must analyze whether the "hypothetical" claim brought by the declaratory-defendant would raise a federal question. *See Cedar-Sinai Medical Ctr. v. Watkins*, 11 F.3d 1573 (Fed. Cir. 1993). If the Court would have jurisdiction over the hypothetical claim, then it has jurisdiction over the declaratory judgment claim. For patent cases, a court's jurisdiction extends over cases where the well-pleaded complaint establishes that either (1) federal law creates the cause of action; or (2) that the plaintiffs right to relief necessarily depends on resolution of substantial question of federal patent law. *See Christanson v. Colt Industries Operating Corp.*, 486 U.S. 800, 808,100 L. Ed. 2d 811, 108 S. Ct. 2166 (1988).

The Court holds that a district court could assert jurisdiction over the hypothetical plaintiffs claim in this case. In Count I, MedImmune seeks a declaration that its product does not fall within the category of a "licensed product" within the meaning of the Agreement, because it would not infringe the '715 patent in the absence of the Agreement. The reverse claim would be that MedImmune's product is a "licensed product" because it *would* infringe the '715 patent absent the agreement. In the hypothetical claim, as in this claim, patent law and issues would be dispositive.

That a hypothetical reverse claim would look like anything but a claim dealing with infringement is an idea discredited by the actual claim filed in California which, by the Universities' own terminology, was the *mirror-image* claim. In paragraph 25 of the Complaint filed in California, the Universities, who presumably draft their allegations with exactitude, state: Plaintiffs hereby seek a declaratory judgment that MedImmune owes royalties under the Sublicense Agreement *because the '715 Patent is valid and enforceable and MedImmune would be liable for patent infringement but for the Sublicense Agreement.* Defendants now assert, despite the allegation being absent from the original complaint in the mirror-image action, that they would assert the theory that MedImmune is equitably estopped from claiming that its product does not infringe the '715 patent. As the Court reads it, however, that would not be a different legal theory (as the Universities term it), but a different legal claim entirely.

For however confusingly Count I maybe worded, it is evident from the Count that at its heart lies the issue of patent infringement. If the Count were turned around in a hypothetical claim, then the declaratory-defendants would assert, just as they did, that the license is enforceable and that Synagis® would infringe the '715 patent in the absence of the license. The Court has jurisdiction over Count I.

B) *"Actual Controversy" Requirement*

The Universities do not dispute that there are federal question grounds for the assertion of jurisdiction over Counts II and III. They argue, however, that there is no actual controversy because MedImmune is not under a reasonable apprehension of suit. Essentially, they assert that while under license, MedImmune is not under a reasonable threat of an infringement suit. They argue that MedImmune must first breach the licensing agreement (e.g., stop paying royalties) before an actual controversy can arise. The Court believes

that the relevant case law on the issue does not demand such a result.

In a more typical case, a patent holder approaches an alleged infringer (with whom the patent holder has no prior contractual relationship), accusing the other party of infringement and threatening suit. The Federal Circuit has made it clear, however, that even a party still subject to a licensing agreement may sue the other party for declaratory relief. *See C.R. Bard v. Schwartz*, 716 F.2d 874, 880 (Fed. Cir. 1983) ("We reject the blanket approach [that says] that there can never be an apprehension of a federal infringement suit and thus no controversy while a license is still in effect."). In such a situation, the district court is asked to determine whether under the totality of the circumstances, the plaintiff faces a reasonable apprehension of an infringement suit.[5]

The Court finds that under the totality of the circumstances, there is a reasonable apprehension of an infringement suit (even in the absence of a breach of the licensing agreement) sufficient to create an "actual controversy". Although the par-

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[5] It is noteworthy to reference the Circuit split that the Federal Circuit was considering in *Bard*. The Third Circuit had held that when a licensing agreement is in effect, no threat of an infringement suit is possible; as such, a potential licensee-plaintiff would have to breach the licensing agreement, thereby creating the imminent threat of such a suit. *See Thiokol Chem. Corp. v. Burlington Industries, Inc.*, 448 F.2d 1328 (3rd Cir. 1971), *cert, denied*, 404 U.S. 1019, 301 L. Ed. 2d 668, 92 S. Ct. 684 (1972). Although the Universities do not specifically endorse this position, they seem to argue that no licensee can bring suit against the licensor until the licensee has first renounced the license agreement. The Second Circuit took a different position, finding that an actual controversy could exist even though the licensing agreement was still in effect. *See Warner-Jenkinson v. Allied Chem. Corp.*, 567 F.2d 184 (2nd Cir. 1977). The Federal Circuit explicitly renounced the holding in *Thiokiol*, holding that the predicate step of breaking the license agreement was not required. And the Court disagrees with the Universities' interpretation of *Bard* as signifying that a licensee must stop paying royalties as a separate predicate to suit.

ties are under license, there is a clear and concrete dispute between them about whether Synagis® infringes on the '715 patent. It is beyond doubt that were MedImmune to breach the licensing agreement, Defendants would immediately file suit on infringement (and possibly other) grounds. The Universities contend that a licensee has no choice but to first withhold licensing royalties before a threat of an infringement suit can arise. Under the circumstances in the present case, the Court finds that such a threat can exist in the absence of any breach of the licensing agreement.[6]

The Court understands that (in more ways than one) this case is somewhat atypical. But as is evidenced by the suit filed in California, both sides have shown an eagerness to resolve the dispute between them.[7] To the extent that the Court finds that a licensee (wishing to adjudicate questions of infringement and invalidity without the necessity of breaking a license agreement) may under the appropriate circumstances bring a suit for declaratory relief, other courts seem to concur. *See Technical Concepts, L.P. v. Zurn Industries*, 2002

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[6] At oral argument, the Universities repeatedly argued that the apprehension of suit is unreasonable because there are too many "future contingencies" between the current state of affairs and a potential infringement suit. The Court disagrees, finding only one: MedImmune's breach of the licensing agreement. In a sense, all declaratory judgment actions involves "future contingencies" in that they involve a party seeking relief *before* certain future legal action has occurred. The purpose of these type of actions is to remove the harmful uncertainty that arises when a party is unsure as to its legal position. In any event, the Court does not believe that current Federal Circuit law requires the withholding of royalties in order to convert a vague or generalized apprehension into a reasonable and concrete one.

[7] The Universities beseech the Court to "follow" the analysis of Judge Breyer in the California action. Again, their reliance on that case is misplaced. The California court did *not* hold that there was no "actual controversy" due to the licensing agreement. Instead, the court there held that the ruling in this case would eliminate any potential infringement suit.

U.S. Dist. LEXIS 16925 (N.D.Ill. 2002) (no need to rescind a licensing agreement prior to suit)[8]; *American Hospital Supply Corp. v. Damon Corp.*, 597 F. Supp. 445, 447 (N.D.Ill. 1984) (*citing Precision Shooting Equipment Co. v. Allen*, 696 F.2d 313, 318 (7th Cir. 1981) ("In such a case, a licensee need not sit back and continue to wonder if it is justly paying royalties or merely paying a bribe to the patentee not to threaten him with business disruption and a possible damage suit if he terminates royalty payments.").[9] As MedImmune is faced with a reasonable apprehension of suit, it has sufficiently shown an "actual controversy".[10]

III. *BURDEN OF PROOF*

The principles and findings enunciated in the Court's analysis as to subject matter jurisdiction inform the Court's

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[8] In assessing whether the declaratory-plaintiff had a reasonable apprehension of suit, even in the absence of a breach of the licensing agreement, the *Technical* court stated: "[defendant] did not explicitly rule out future litigation during that conversation, and thus [plaintiff] could reasonably fear, based on [defendant's] actions, that a lawsuit *would follow closely on the heels of the Agreement's termination.*" *Id.* at *17 (emphasis added).

[9] The cases cited by the Universities do not aide their cause. For example, *Chattanooga Corp. v. Klingler*, 621 F. Supp. 756 (E.D.Tenn. 1985) is unpersuasive for two reasons. First, in *Chattanooga*, the Court noted that the declaratory-defendant had never alleged infringement. Here, Centocor has alleged infringement from the very beginning of the relationship between the disputants. Second, the case relied on a proposition—a licensee still paying under a license has no apprehension of suit—that is inconsistent with *Bard*.

[10] Although the two-pronged test cited by the Universities has not evidently been applied in these type of cases, even if the Court applied it here, the result would be the same. The first prong is satisfied by the Court's holding that a reasonable apprehension exists. The second prong is easily satisfied: MedImmune is, according to Defendants, currently infringing on the '715 patent. *See Intellectual Prop. Dev., Inc. v. TCI Cablevision, Inc.*, 248 F.3d 1333, 1340-41 (Fed. Cir.), *cert, denied*, 534 U.S. 895, 151 L. Ed. 2d 154, 122 S. Ct. 216 (2001).

determination as to who bears the burden of proof on Count I of the Amended Complaint. MedImmune's position is that since Count I deals with the question of whether Synagis® infringes the '715 patent, Defendants bear the burden of proof as to Count I. Defendants argue that Count I is essentially a contract claim-an argument somewhat supported by the Count's title-and that, as such, MedImmune bears the burden as to Count I. Reduced to its core, Defendants' argument is that Plaintiff must first breach the licensing agreement before it can bring a more typical declaratory judgment non-infringement action. The Court concludes that, as the patent holders, Defendants bears [*sic*] the burden of proof on infringement and thus bear the burden as to Count I.

Generally, "[t]he burden always is on the patentee to show infringement." *Under Sea Industries, Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987). Thus, in a typical patent infringement declaratory judgment case where the declaratory plaintiff seeks a holding of non-infringement, the patent holder retains the burden of proof despite being the nominal defendant. *See, e.g., Glenayre Elecs., Inc. v. Jackson*, 2003 U.S. Dist. LEXIS 2332, *47 (N.D.Ill. 2003). This relates in some ways to the "flexible approach" to determining burden issues, which requires, as this Court has put it, that the party who "asserts the affirmative of an issue" must hold the burden of proof. *See Stash, Inc. v. Palmguard Int'l, Inc.*, 937 F. Supp. 531, 534, n.8 (D. Md. 1996).

It is evident, therefore, that the determination of who bears the burden of proof hinges on the Court's framing of the issue in Count I. The question of who is "asserting the affirmative" is tied to what issue is to be resolved in Count I. Despite its somewhat awkward phrasing, the Court concludes that the issue to be determined in Count I is infringement; i.e., the determination as to whether Synagis® is a "licensed product" will be resolved by the question of infringement. Evidence will be presented by both sides on the question of in-

fringement. The fact-finder will then determine whether the '715 patent is infringed by Synagis®. That determination will result in the decision as to who prevails on Count I.[11]

Centocor seems to admit that if MedImmune had breached the licensing agreement, Defendants would bear the burden of proof on infringement. It argues, however, that absent a breach of the licensing agreement, it would lead to an "absurd result" to allow the burden of proof to reside with the patent holders. Notably, Centocor does not cite to any authority for the proposition that only a licensee who has breached the licensing agreement may bring a declaratory judgment act [*sic*] for non-infringement. In fact, the Court does not agree that there is anything "absurd" or "unjust" about the result of its decision. The parties bargained at arms-length to formulate the terms of the Agreement. Presumably, in that both parties signed the agreement, each side believed that it was receiving adequate consideration. Centocor argues that MedImmune should not now be allowed to "have it both ways," enjoying the benefits of the Agreement while suing for declaratory relief. But the Court is compelled to repeat what it has already stated: *both* parties are mutually benefitting from the agreement being in effect. MedImmune has benefitted from immunity from suit and Centocor has equally benefitted from royalty payments.

The change in the status quo sought by MedImmune is a finding that it does not have to pay those royalty payments any more. That determination, in the Court's view, comes down to infringement. For however Count I is framed, the issue presented is whether MedImmune's product infringes

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[11] This conclusion is premised on the fact that no *other* issues as per the licensing agreement will arise during the course of the litigation. If MedImmune seeks to add other arguments to the mix about whether Synagis® is a "licensed product" (i.e., contractual intentions), the Court might be asked to determine anew at that point whether MedImmune has improperly sought to transfer the burden to the opposite side.

the '715 patent. As such, in accordance with the general rule in infringement action, the patent holders must show that Synagis® infringes.

IV. *FAILURE TO PLEAD WITH PARTICULARITY*

The Universities have also moved this Court to dismiss or grant judgment on the pleadings on the claims asserted in Medimmune's Amended Complaint for failure to plead these claims with sufficient particularity. Specifically, the Universities contend that: (1) Medimmune provides no factual or legal basis for its patent invalidity claim which, therefore, fails to satisfy Rule 8(a); and (2) Medimmune's allegation that the '715 patent is unenforceable due to inequitable conduct contains insufficient factual support to satisfy the particularity requirement of Rule 9(b). Medimmune responds that the Amended Complaint sufficiently sets forth the grounds of a claim for invalidity and the factual allegations in support of a claim for inequitable conduct. The Court makes the following conclusions. First, Medimmune's patent invalidity claim does not satisfy Rule 8(a) and, therefore, Medimmune will be granted leave to amend its Amended Complaint to include the grounds upon which its invalidity claim rests. Second, Medimmune's unenforceability due to inequitable conduct claim meets the particularity requirement of Rule 9(b) but, if during the course of preparing its Second Amended Complaint Medimmune is able to provide factual allegations adding specificity to its claims of inequitable conduct, such information should be provided.

A) *Rule 8(a)*

To satisfy Rule 8(a), a pleading which sets forth a claim for relief must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The purpose of the "short and plain statement" is to give the defendant fair notice of what the plaintiffs claim is and the grounds upon which it rests. *Conley v. Gibson*, 355

U.S. 41,47, 2 L. Ed. 2d 80, 78 S. Ct. 99 (1957). "This simplified notice pleading standard relies on liberal discovery rules and summary judgment motions to define disputed facts and issues and to dispose of unmeritorious claims." *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 512, 152 L. Ed. 2d 1, 122 S. Ct. 992 (2002). However, vague and conclusory allegations are insufficient to satisfy the notice pleading requirements of the Federal Rules of Civil Procedure. *Sampson v. Welch*, 900 F.2d 33, 35 (4th Cir. 1990).

In Count II of the Amended Complaint, Medimmune claims that the '715 patent is invalid. In its opposition to the Universities' motion, Medimmune appears to allege prior art and the written description requirement as the grounds for this invalidity claim. However, the Amended Complaint makes no mention of these grounds. Paragraph 33 of the Amended Complaint, wherein Medimmune contends the grounds for its invalidity claim lie, alleges that the Universities misrepresented that conception of the claimed invention occurred before the publication of a critical prior art reference, misrepresented that the claimed invention would work in a wide variety of cell types, and omitted information indicating that the claimed invention would not work in a wide variety of cell types. The Court gleans that this paragraph deals with a charge of inequitable conduct. However, it appears as though Medimmune attempts to argue additional grounds for its invalidity claim in its opposition motion. Plus, at the motions hearing, Medimmune revealed that it might assert grounds for its invalidity claim that it did not even include in its opposition motion. Medimmune's failure to set forth these grounds in its Amended Complaint renders Rule 8(a) unsatisfied.

The Court will not allow Medimmune to continuously expand the basis for its invalidity claim. In arguing the merits of Count II, Medimmune will be confined to the grounds allegedly supporting invalidity that are set forth in its complaint and satisfy Rule 8(a). Thus, the Court requests that

Medimmune file a Second Amended Complaint, within ten days of entry of the attached order that clearly alleges all grounds upon which its invalidity claim rests.

B) *Rule 9(b)*

Rule 9(b) requires that, "In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge and other condition of mind of a person may be averred generally." Fed. R. Civ. P. 9(b). Inequitable conduct includes affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false information, coupled with an intent to deceive. *Baxter Int'l Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998). Courts generally hold that allegations of inequitable conduct are subject to the particularity requirements of Rule 9(b). *See Rhone-Poulenc Agro S.A. v. Monsanto, Co.*, 73 F. Supp. 2d 537, 538 (M.D.N.C. 1999); *Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.*, 989 F. Supp. 1237, 1247 (N.D. Cal. 1997). Accordingly, the "circumstances" required to be pled with particularity are the time, place, and contents of the inequitable conduct, as well as the identity of the parties responsible for the inequitable conduct. *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999). Court's [*sic*] recognize that the purpose behind requiring such particularity is to provide a defendant fair notice of the substance of a plaintiffs claim so that the defendant can formulate a defense. *See Michaels Bldg. Co. v. Ameritrust Co., N.A.*, 848 F.2d 674, 679 (6th Cir. 1988).

In Count III of the Amended Complaint, Medimmune alleges that the '715 patent is unenforceable due to inequitable conduct. The Court feels satisfied that the claims of inequitable conduct contained in the Amended Complaint comply with the particularity requirement of Rule 9(b). Medimmune pleads the time and place of the alleged inequitable conduct with the statement, "[D]uring prosecution before the

PTO." Medimmune's specification that the "Applicants" are responsible for the inequitable conduct satisfies the identity requirement because Medimmune states the names of the patent applicants in Paragraph 12 of the Amended Complaint. The identification of the Ochi publication as the prior art in part (a) of Paragraph 33 and statement "suggesting that the claimed invention would work in a wide variety of cell types" in part (b) of Paragraph 33 specify the content of the alleged misrepresentations. The statement in part (b) of Paragraph 33, "omitting or concealing information to the contrary," implies omission of information suggesting that the claimed invention would not work in a wide variety of cell types. As such, it specifies the content of the alleged omission. The Amended Complaint sufficiently alleges the materiality of the inequitable conduct when it states that, "[T]he '715 patent would not have issued but for these misrepresentations and/or omissions." Furthermore, Rule 9(b) allows intent to deceive to be averred generally, which Medimmune has done. The Court's conviction in making these findings is bolstered by the fact that Defendants appear to have notice of the substance of the inequitable conduct claims contained in Paragraph 33 of the Amended Complaint.

However, as indicated above, the Court is unsettled by Medimmune's seeming desire to argue that the '715 patent is invalid based on grounds that are not specified in the Amended Complaint, and thereby requests that the Amended Complaint be amended. Although Medimmune's unenforceability due to inequitable conduct claim technically satisfies Rule 9(b), if during the process of amending the Amended Complaint Medimmune is able to provide information that elaborates on the factual support for its inequitable conduct claim, the Court requests that this information be included in the Second Amended Complaint.

The Court will not look fondly upon a rehashing of the same arguments entertained herein in a second motion to

dismiss or motion for judgment on the pleadings filed by the Universities. Discovery must be allowed to proceed and, subsequent to the requests made above, the Universities should have sufficient notice for the preparation of their defense. Arguments on the merits of Medimmune's allegations should be reserved for motions for summary judgment, which will be appropriate after this litigation has moved beyond its current stall in the beginning stages of discovery.[12] In sum, the Universities' motion to dismiss and/or motion for judgment on the pleadings will be granted in that Medimmune will be required to file a Second Amended Complaint in accordance with this opinion.

V. *PROTECTIVE ORDER*

The issue of whether counsel for Medimmune, Elliot Olstein, esq. ("Olstein"), should be allowed to view confidential and highly-confidential materials during the course of the litigation has been exhaustively argued by both parties in memoranda and in oral argument. Defendants argue that Olstein is a "competitive decision-maker" for Medimmune and that he therefore should be either denied access to the material or should refrain from prosecuting patents on the same subject matter as the litigation. Plaintiff denies that Olstein should be denied access at all but have [*sic*] offered to restrict some of Olstein's future patent prosecution.

Although the issue is a "close-call", the Court concludes Olstein's offer should be adopted and that Olstein should be allowed to view confidential and highly-confidential material as he is not a "competitive decision-maker". The law on

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[12] During the course of oral argument, the Universities made many arguments as to the *strength* of Medimmune's inequitable conduct claim. They argued that based upon discovery they had received, Medimmune could not show inequitable conduct. Those arguments are clearly premature at the motion to dismiss stage. The Universities will not be allowed to try the inequitable conduct claim on the pleadings alone.

counsel's access to confidential material is governed by the over-arching principles set-out in *United States Steel Corp. v. United States*, 730 F.2d 1465 (Fed. Cir. 1984). As pronounced by the Federal Circuit, the policy underlying a restriction on counsel's access to confidential materials is the concern that counsel might inadvertently disclose the confidential material learned during the course of litigation. *See id.* at 1468. The competing interests to be evaluated in determining the outcome of such a dispute are one party's right to broad discovery and the other party's ability to protect its confidential materials from misuse by competitors. *See Brown Bag Software v. Symantec Corp.*, 960 F.2d 1465,1469-70 (9th Cir.), *cert. denied sub nom., BB Asset Mgmt. v. Symantec Corp.*, 506 U.S. 869, 121 L. Ed. 2d 141, 113 S. Ct 198 (1992). The inquiry focuses on whether counsel can be a deemed a "competitive decision-maker", which the Federal Circuit says is shorthand for "a counsel's activities, association, and relationship with a client that is such as to involve counsel's advice and participation in any or all of the client's decisions (pricing, product design, etc.) made in light of similar or corresponding information about a competitor." *U.S. Steel*, 730 F.2d at 1468, n.3. A counsel's title as "in-house" or "retained" will not be dispositive on the issue. *See id.* In addition to determining whether a counsel is a competitive decision-maker, the Court must also analyze whether denying counsel access to confidential material would work a substantial hardship on one of the parties. *See id.*

The Court is extremely sensitive to the confidentiality concerns of a party litigating a case such as this one. Nevertheless, the Court concludes that the Universities' argument amounts to a *per se* prohibition on the use of litigation counsel who also prosecute patents. Other than Olstein's status as a patent prosecutor for MedImmune, the Court finds no other indicators that would warrant denying him access to confidential materials. MedImmune's proposed wording for the Protective Order will, therefore, be adopted.

The Universities correctly note that in-house counsel have already been denied access to confidential materials in this case. They have argued that Olstein, while not an employee of MedImmune, is effectively "in-house" counsel for MedImmune. The record does not support such a characterization nor does it support a conclusion that Olstein is a competitive decision-maker. No evidence has been proffered that Olstein participates in MedImmune's decision-making in relation to competitors in biotechnology field. He does not apparently participate in product design, pricing or marketing. His law firm and MedImmune do not share employees. The Court views Olstein's role as one of patent prosecutor in the typical sense: he takes products that MedImmune has already-developed and brings them before the Patent Office. To adopt the Universities [*sic*] position would inexorably lead to the conclusion that *no* attorney, whether in-house or retained, could prosecute patents for a client while still working as litigation counsel for that client. Such a result would run contrary to Federal Circuit law.

In any event, Olstein's proposal works to provide some protection to the Universities. The Universities have claimed that no information dealing with the "making" of DNA recombinant technology can be separated from information dealing with the "use" of DNA recombinant technology. They argue that it would be overly burdensome to force the Universities to exact portions of the discovery they plan to disclose. To the extent, however, that the Court's holding could allow for Olstein to have no restriction whatsoever to viewing the materials, the Court believes that his proposal sufficiently covers any potential concern that might arise.[13]

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[13] The Court's decision runs contrary to a holding in another district court which denied retained counsel access to confidential materials because counsel worked prosecuting patents for one of the parties. *See Interactive Coupon Marketing Corp. v. H.O.T.! Coupons LLC*, 1999 U.S. Dist. LEXIS 12437 (N.D.Ill. 1999). The Court disagrees with the reasoning applied in *Interactive*

Although the Universities have attempted to discount the possibility, the Court also believes that denying Olstein access would work a hardship on *MedImmune*. Having worked for MedImmune for nearly twelve years, Olstein could provide a significant amount of assistance to the claims of non-infringement. That MedImmune has hired other retained lawyers to also represent it does not mean that Olstein's participation is not important to MedImmune.

The Court finds support for its conclusion in *Sibia Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, 1997 U.S. Dist. LEXIS 24130 (S.D.Cal. 1997). There, the Magistrate held that a party's patent counsel should be denied access to confidential materials because of his current and on-going patent prosecution for the client. In overturning the Magistrate's decision, the district court made a number of pertinent observations. First, the court noted that *Motorola, Inc. v. Interdigital Tech. Corp.*, 1994 U.S. Dist. LEXIS 20714 (D.Del. 1994), a case relied upon by the Universities, represented an extension of the current Federal Circuit law on the subject. *See id.* at *19. Second, the court noted that counsel in that case was not easily analogized to in-house counsel because he represented many other biotech firms, he did not serve on the client's board of directors, and his firm did not exchange any employees with the company. Third, and most importantly, the indicia of competitive decision-making were not present. Counsel was not involved in pricing or design, nor was he involved in scientific research. In short, counsel prosecuted patents for products that were already developed. *See id.* at *22-23.

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because, in the Court's view, it amounts to a *per se* prohibition on patent counsel. If "shaping" patent applications amounts to competitive decision-making, the Court has trouble imagining a patent prosecutor who would not meet that standard. In any event, here there has been no showing that Olstein does anymore than bring the patents before the Patent Office. There has been no showing that he actively participates in MedImmune's internal decision-making process *vis a vis* its competitors.

Similarly here, all that has been shown is that Olstein prosecutes patents in the biotech field for MedImmune. In that regard, he is not that different from the other retained counsel in the case. He prosecutes patents for MedImmune, but he also works for many other biotech clients in their patent work. The key is "competitive decision-making": as he is not a competitive decision-maker, he does not need to be restricted in the activities he pursues for MedImmune. But his proposal offers the Universities additional protection above and beyond what is required. His proposal should be adopted.[14]

VI. *CONCLUSION*

The Universities' motion to dismiss for lack of subject matter jurisdiction will be denied because the Court has found jurisdiction over all three Counts. The burden of proof in Count I will lie with the declaratory-defendant patent holders. The Universities' motion to dismiss on particularity grounds will be granted without prejudice, and MedImmune will be granted leave to file a Second Amended Complaint within ten (10) days of the entry of this Order, after which time Defendants will have ten (10) days to file a responsive pleading. Lastly, MedImmune's counsel will be allowed to view confidential materials subject to the restriction that he has proposed. The Court further notes that there are now currently

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[14] Certain cases which denied in-house counsel access to confidential materials can be distinguished on the facts. For example, in *Intel Corp. v. VIA Tech., Inc.*, 198 F.R.D. 525 (N.D.Cal. 2000), the court denied Intel's in-house counsel access to confidential materials in part because of her "interactions with Plaintiffs business unit managers and with her supervisor. . . ." *See id.* at 532. Here, no showing has been made that Olstein has any regular interaction with any supervisors at MedImmune. *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 1998 U.S. Dist. LEXIS 22251 (D.Nev. 1998) is also inapposite because there the Court found that the patent counsel was currently prosecuting patents on the exact same subject matter of the litigation. No such showing has been made here.

pending motions to compel discovery. The Court will be referring all discovery disputes to a Magistrate in furtherance of moving the proceedings in this case forward. An Order consistent with this Opinion will follow.

7/16/2003
Date

/s/
Alexander Williams, Jr.
United States District Judge

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

Civil Action No. AW-02-1135

MEDIMMUNE, INC.,

Plaintiff,

vs.

CENTOCOR, INC., *et. al.*,

Defendant.

MEMORANDUM OPINION

Currently pending before the Court are Defendants' Fourth Motion to Dismiss [213] and Motion to Reopen [239]. The motions have been fully briefed by all parties. No hearing is deemed necessary. *See* D. Md. R. 105.6. Upon consideration of the arguments made in support of, and in opposition to, the respective motions, the Court makes the following determinations.

I. *BACKGROUND*

A. Factual Background

The Court takes the facts necessary for adjudication of the pending motion to dismiss from the Amended Complaint. At the heart of this controversy is a patent which purports to cover "methods for producing functional immunoglobin" and relates to the use of genetically altered cells to generate antibody molecules in the laboratory. The inventors ("Applicants") applied to the United States Patent and Trademark Office ("PTO") on August 27, 1984. The PTO issued the Patent ("'715 Patent") fourteen years later in 1998. The '715

Patent has been assigned to the Universities. Prior to the issuance of the Patent on November 10, 1992, Defendant obtained an exclusive license to the Patent through an agreement with the Universities.[1]

In the years preceding the issuance of the Patent, and prior to Plaintiffs awareness of it, Plaintiff was developing a drug called Synagis® which was approved by the Food and Drug Administration ("FDA") on June 18,1998. Synagis® is a humanized monoclonal antibody that "targets a particular virus or source of disease." These monoclonal antibodies are artificially synthesized using recombinant DNA technology. Plaintiff began selling Synagis® in September 1998, after which it became one of Plaintiffs most important and successful pediatric drugs.

On May 19, 1999, Defendant contacted Plaintiff to inform it that Synagis® was infringing on the '715 Patent. Plaintiff disagreed that Synagis® infringed on the Patent but was concerned about the allegation. Plaintiff responded to Defendant by claiming that Synagis® did not infringe on the Patent. Defendant then proceeded to contact Abbott Laboratories, a party contracted to do business with Plaintiff for Synagis®,

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[1] In the agreement between Centocor and the Universities, the Universities granted a "world-wide" license to Centocor to make, use and sell Licensed Products (which are defined as any Licensed Patent Products or Licensed Non-Patent Products). The Universities reserved the right to use the Patent for not-for-profit research purposes. They also reserved the right to grant non-exclusive sublicenses to four companies with which they were negotiating such agreements, and they reserved the right to bring legal action against any alleged infringer. Among other rights granted to Centocor in the Agreement was the right upon notice to the universities to sue any alleged infringer, subject to the Universities right to bring suit within three months of the notice. Centocor agreed to seek sublicenses with third parties. Centocor's right to sublicense was subject to this restriction: "Any proposed sublicense shall be subject to the prior written approval of Columbia, which approval shall not be unreasonably withheld." Agreement §§ 2,3.1,5.1, 12, 13.4, 13.5(d).

and informed Abbott that the product was an infringement of the Patent. Plaintiff eventually agreed to enter into a Sublicense Agreement with Defendant in which it agreed to pay royalties to Defendant. After the formation of the agreement, Plaintiff claims, *inter alia,* that it came upon information which demonstrated that the Patent was invalid and unenforceable because of, among other reasons, "inequitable conduct" by the Applicants during the patent application process before the PTO.

B. Procedural Background

Plaintiff initiated this action on April 5, 2002. On July 1, 2002, Defendant Centocor filed a Motion to Dismiss for Declaratory Judgment, which was denied by this Court in a memorandum opinion and order dated December 12, 2002. In that order, this Court additionally denied a Motion to Transfer that had been filed subsequently to the Motion to Dismiss and directed Plaintiff to join the other two Defendants to this action. On January 6, 2003, Plaintiff filed an amended complaint in compliance with the Court's order.

On May 5, 2003, Defendants moved to dismiss or for judgment on the pleadings. Subsequently, on May 15, 2003, Defendants filed a Cross Motion to Dismiss for lack of jurisdiction. The first of these motions was granted on July 15, 2003, with leave given to Plaintiff to amend the Complaint. The second motion was denied in the same memorandum opinion and order. On July 30, 2003, Plaintiff filed its second Amended Complaint.

Most recently, on March 22, 2004, Defendants filed a fourth Motion to Dismiss for lack of jurisdiction, based on new law issued by the Federal Circuit March 5, 2004. *See Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004) (holding declaratory action not properly before the court where licensing agreement is in place and licensee continues to pay royalties pursuant to contract). On May 20, 2004, this

Court entered an order staying the proceedings, based upon the assertion made by Plaintiff that the Federal Circuit had not yet ruled on Gen-Probe's Petition for Rehearing *En Banc*. Five days later, Defendants filed a Motion to Reopen based upon a disposition sheet from the Federal Circuit indicating that the appellate court denied Gen-Probe's petition May 24, 2004.

II. *DISCUSSION*

A. Standard of Review

Under Fed. R. Civ. P. 12(b)(6), a court should not dismiss a complaint "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46. The Fourth Circuit has stated,

> [A] Rule 12(b)(6) motion should only be granted if, after accepting all well-pleaded allegations in the plaintiffs complaint as true and drawing all reasonable factual inferences from those facts in the plaintiffs favor, it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief.

Edwards v. City of Goldsboro, 178 F.3d 231, 244 (4th Cir. 1999). When considering a motion under Fed. R. Civ. P. 12(b)(l), the Court must first determine which way the motion has been presented. If it is contended that the Plaintiff has failed to allege sufficient facts upon which to based subject matter jurisdiction, then the Plaintiff is afforded all of the same procedural protections as are available under the Rule 12(b)(6) standard. *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982).

B. Analysis

1. *Motion to Reopen*

For the very reasons cited by Defendants, the Court finds Plaintiff's argument stemming from Gen-Probe's attempt to bring its appeal before the Supreme Court unpersuasive. The Supreme Court does not have time to hear but a small percentage of the cases with parties seeking to present arguments before it. In any event, unless and until the decision is over-turned by the Supreme Court, the Federal Circuit's opinion is controlling law over the matter presently before this Court. Accordingly, the Court will address the issues presented in the Fourth Motion to Dismiss. However, in light of the decision reached with respect to that motion, the Court will not reopen the case, but simply issue its decision, keeping the case closed.

2. *Fourth Motion to Dismiss*

In *Gen-Probe,* the Federal Circuit analyzed in depth the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a). The Court then, faced with facts identical in all material aspects to the instant case, found that a complainant fails to meet that requirement when it chooses to enter into an agreement to pay royalties to the owner of a patent and then abides by the terms of that contract. The appellate court launched into a discussion of a case cited prominently by Plaintiff, *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969) (finding that the licensee is not barred from challenging a patent's validity based upon that license alone). Citing *Studiengesellschaft Kohle m.b.H. v. Shell Oil, Co.*, 112 F.3d 1561 (Fed. Cir. 1997), the Court found the following:

> While that case did not discuss jurisdiction under the Declaratory Judgment Act, this court stated: [A] licensee . . . cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for

> ceasing payment of royalties is because it has deemed the relevant claims to be invalid. *Shell Oil*, 112 F.3d at 1568. This language posits that a licensee must, at a minimum, stop paying royalties (and thereby materially breach the agreement) before bringing suit to challenge the validity or scope of the licensed patent.

Gen-Probe, 359 F.3d at 1381.

This Court not only finds the conclusions of the Federal Circuit compelling, but, unlike the arguments put forth by Plaintiff, this Court finds them controlling as well. Plaintiff maintains that subject matter jurisdiction is not a substantive issue, but instead a procedural one and thus, Fourth Circuit law should prevail. In support of this contention, Plaintiff cites *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999). However, in that same opinion, on that same page, the Federal Circuit stated as one of the questions to which Federal Circuit law applies, "whether there is a sufficient controversy between the parties to permit an accused infringer to bring an action seeking a declaratory judgment of patent infringement or invalidity." *Id.* (citing *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 954-55 (Fed. Cir. 1987). Since the Court finds that *Gen-Probe* is controlling over the matter currently before it, the Court will not reach the broader arguments raised by Plaintiff addressing its belief that the decision was wrongly decided.

III. *CONCLUSION*

For the reasons stated above, the Court will DENY Defendants' Motion to Reopen, but will GRANT Defendants' Fourth Motion to Dismiss. An Order consistent with this Opinion will follow.

June 17, 2004
Date

/s/
Alexander Williams Jr.
United States district Judge

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

Civil Action No. AW-02-1135

MEDIMMUNE, INC.,

Plaintiff,

vs.

CENTOCOR, INC., *et. al.*,

Defendant.

ORDER

For the reasons stated in the accompanying Memorandum Opinion dated June 17, 2004, IT IS this 17th day of June, 2004 by the United States District Court for the District of Maryland, hereby ORDERED:

1. That Defendants' Motion to Reopen [Paper no. 239] BE, and the same hereby IS, DENIED;

2. That Defendants' Fourth Motion to Dismiss [Paper no. 213] BE, and the same hereby IS, GRANTED; and

3. That the Clerk of the Court transmit copies of this Opinion and Order to all counsel of record.

/s/

Alexander Williams, Jr.
United States District Judge

APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

[Filed Aug. 25, 2005]

ORDER

A petition for rehearing en banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the APPELLEES, and the matter having first been referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on September 1, 2005.

FOR THE COURT,

/s/ Jan Horbaly
JAN HORBALY
Clerk

Dated: August 25, 2005

Cc: Harvey Kurzweil
John C. Dougherty, Teresa M. Corbin

MEDIMMUNE V CENTOCOR, 04-1499
(DCT - 8:02-CV-01135)

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

APPENDIX F

CONSTITUTIONAL AND STATUTORY PROVISIONS

Article III of the Constitution of the United States provides in relevant part:

> SECTION 2. The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States . . . .

Title 28 U.S.C. § 1331 provides:

> The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.

Title 28 U.S.C. § 1338(a) provides:

> The district courts shall have original jurisdiction of any civil action arising under any act of Congress relating to patents, plant variety protection, copyrights and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases.

Title 28 U.S.C. § 2201(a) provides:

> In any case of actual controversy within its jurisdiction, except . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such a declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

Supreme Court, U.S.
FILED
DEC 27 2005
OFFICE OF THE CLERK

No. 05-656

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,

Petitioner,

v.

CENTOCOR, INC., *et al.*,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Circuit correctly decided that there is no case or controversy over a patent declaratory judgment action by a plaintiff-licensee in good standing who seeks to challenge a licensed patent where (a) the plaintiff's continued royalty payments ensure that it is maintaining all of the benefits of its license and has no reasonable apprehension of an infringement suit, and the plaintiff is seeking to challenge the licensed patent on the very same grounds that it raised during the license negotiations to obtain more favorable terms, and (b) allowing the action to proceed would subvert the purpose of the license by providing the licensee a safe platform from which to force the licensor to litigate in contravention of its own promise not to sue and with no ability to recover its full measure of damages.

CORPORATE DISCLOSURE STATEMENT PURSUANT TO SUPREME COURT RULE 29.6

Respondent Centocor, Inc. ("Centocor") has one parent corporation, Johnson & Johnson, which is the only publicly-traded corporation that owns 10% or more of Centocor's stock. The other two respondents, The Trustees of Columbia University in the City of New York and The Board of Trustees of the Leland Stanford Junior University ("the Universities"), are private academic institutions. No parent or publicly-held entity has any ownership interest in the Universities.

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IN THE

Supreme Court of the United States

No. 05-656

MEDIMMUNE, INC.,

Petitioner,

v.

CENTOCOR, INC., *et al.*,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

Respondents respectfully request that this Court deny the petition for writ of certiorari seeking review of the Federal Circuit's decision in this case.

STATUTORY PROVISIONS INVOLVED

28 U.S.C. § 1331 (federal question jurisdiction), 28 U.S.C. § 1338(a) (federal jurisdiction over, among other things, patents), and 28 U.S.C. § 2201(a) (Declaratory Judgment Act) are reproduced at Petitioner's Appendix ("Pet. App.") 41a. Petitioner also alleged that the district court had jurisdiction under 28 U.S.C. §§ 2202 and 1332.

STATEMENT OF THE CASE

A. Background Leading To The Litigation

This case involves U.S. Patent No. 5,807,715 ("the '715 patent"). The '715 patent issued on September 15, 1998 and is entitled *Methods and Transformed Mammalian Lymphocytic Cells for Producing Functional Antigen-Binding Protein Including Chimeric Immunoglobulin and Fragments.* The patent reflects the work of prominent research scientists in the field of monoclonal antibody technology. The Trustees of Columbia University in the City of New York ("Columbia University") and The Board of Trustees of the Leland Stanford Junior University are the assignees of the patent, and Centocor is the exclusive licensee.

Petitioner, MedImmune, Inc. ("MedImmune"), learned of the '715 patent shortly after it issued and called Columbia University to inquire about a license. CAA. 1200-01, 1212.[1] A representative of Columbia University informed MedImmune that Centocor was the exclusive licensee. CAA. 1212. Around that same time, MedImmune asked its regular outside patent counsel to evaluate the '715 patent, including whether it was valid and infringed by MedImmune's product Synagis®. CAA. 1200-01.

Centocor, as part of its sublicensing obligations to the Universities, wrote MedImmune on May 19, 1999, to offer it a sublicense to the '715 patent. CAA. 1223. The letter did not mention or threaten litigation. *Id.* In response to Centocor's offer to discuss a license, MedImmune advised Centocor that "MedImmune and its outside patent counsel have reviewed [the '715] patent . . . and have concluded that we do not infringe any valid patent claim." CAA. 573. MedImmune continued to consult with outside counsel and

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[1] Citations to "CAA." are to the joint appendix filed in the Court of Appeals.

hired another law firm for a second opinion on the issues of infringement and invalidity. CAA. 1247, 1418.

In May 2000, following talks between business and legal representatives of both companies, representatives of MedImmune and Centocor met to discuss the terms of a possible sublicense. CAA. 1511-12. During the May 2000 meeting, MedImmune again asserted that the '715 patent was not infringed or valid, and also claimed that MedImmune could design around the patent. CAA. 1421-28. Notwithstanding these arguments, the parties began extensive negotiations over the terms of the sublicense, including the royalty rate. CAA. 1223. Over the next several months, Centocor twice lowered its proposed royalty rate and agreed to forego past royalties for a two-year period in an effort to reach a compromise and after MedImmune voiced concerns about its other royalty obligations on Synagis®. CAA. 1424-25.

MedImmune executed the Sublicense Agreement on December 29, 2000, and began paying royalties on Synagis®. Each MedImmune officer involved in the negotiations testified that MedImmune entered into the Sublicense Agreement and began to pay royalties to eliminate any risk of litigation and an injunction against Synagis® and to cap its damages. CAA. 1220-21, 1229-32, 1386-87, 1500. Synagis® is the only product for which MedImmune has ever paid royalties under the Sublicense Agreement. CAA. 1220.[2]

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[2] As required by Supreme Court Rule 15(2), Respondents point out perceived misstatements in the Petition. The Petition states that Centocor threatened litigation and forced MedImmune to enter into the Sublicense Agreement and pay royalties. *See* Pet. at 3, 21. While these statements have no bearing on whether a case or controversy exists over the present action, because the parties' Sublicense Agreement resolved any disputes the parties may have had concerning the '715 patent and both sides are performing under the Agreement, Respondents nevertheless point out that the statements are inaccurate. MedImmune relied below solely upon an email and conversations between principals of the parties in support of its

Centocor, the Universities, and the inventors ordered their affairs around those royalty payments, and had no reason to suspect that MedImmune wanted to undermine the agreement. Meanwhile, mere days after MedImmune executed the Sublicense Agreement, MedImmune faxed a copy of the agreement to its current litigation counsel. CAA. 1413-14. For at least a year after the Sublicense Agreement was executed, MedImmune assessed its litigation options with respect to the '715 patent. MedImmune's Board of Directors authorized the filing of the lawsuit after being briefed repeatedly on the matter between February 15, 2001 (less than two months after the Sublicense Agreement was signed) through at least February 21, 2002. CAA. 1266, 1272, 1274, 1284, 1291. The minutes from MedImmune's February 21, 2002 Board of Directors' meeting reveal that the decision to file suit was based upon purely financial considerations. CAA. 1291.

On April 5, 2002, MedImmune filed a declaratory judgment action against Centocor in the United States District Court for the District of Maryland. CAA. 42. The complaint sought a declaration of MedImmune's rights and obligations under the Sublicense Agreement, and alleged that Synagis® did not infringe any of the claims of the '715 patent and that the patent was invalid and unenforceable. CAA. 42-59. MedImmune did not stop paying royalties to Centocor before filing its complaint. It has continued to make royalty payments throughout this litigation, and has stated that it does not intend to terminate the Sublicense Agreement. CAA. 515.

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allegations of threats and pressure. These communications, however, were congenial and reflected nothing more than a desire on Centocor's part to finalize the agreement. CAA. 1576, 1568, 2695-97, 1565-67, 131, 2697. Moreover, MedImmune's principal failed to substantiate MedImmune's allegation of threats at his deposition. CAA. 2525-27. Finally, MedImmune has waived any claim of duress in this case. *See* CAA. 515.

Because MedImmune's original April 2002 complaint was filed against Centocor alone and did not name the Universities (the owners of the '715 patent), the Universities and Centocor filed on July 9, 2002, a mirror-image declaratory judgment action against MedImmune in the United States District Court for the Northern District of California (the "California Action"). CAA. 135-43. The California Action was filed in order to add the Universities to the case in a forum in which they were subject to personal jurisdiction (*see* CAA. 138), and because California was a more convenient forum for key inventorship- and patent prosecution-related fact witnesses. CAA. 89.

MedImmune moved to dismiss the California Action for failure to state a claim upon which relief can be granted under the first-filed doctrine and/or under the Court's discretion to decline to exercise jurisdiction under the Declaratory Judgment Act. On October 21, 2002, the California district court granted MedImmune's motion to dismiss. CAA. 1405-11. The case was dismissed for two reasons: (1) because there was "no indication that MedImmune would discontinue performance of its obligations under the sublicense and thus infringe the patent," and thus "there is no actual controversy to satisfy the Declaratory Judgment Act"; and (2) in deference to the previously-filed Maryland action. CAA. 1409-11.

B. The Proceedings Before The District Court

The Universities initially filed a motion to dismiss for lack of a case or controversy in the present action on June 30, 2003. The District Court denied that motion. On March 5, 2004, the Federal Circuit issued its decision in *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004). In the *Gen-Probe* decision, the Federal Circuit, applying its two-part case or controversy test, held that a district court does not have subject matter jurisdiction over a licensee's declaratory judgment suit when the licensee is in good standing and

continues to pay royalties under the license agreement. *Id.* at 1380-82. The Federal Circuit explained that the license, "unless materially breached, obliterated any reasonable apprehension of a lawsuit," and that once the licensor and licensee "formed the license, an enforceable covenant not to sue, the events that led to the formation [of the license] became irrelevant." *Id.* at 1381.

In light of the *Gen-Probe* decision, Respondents again filed before the District Court a motion to dismiss for lack of jurisdiction. In dismissing the action below, the District Court found that MedImmune, like the licensee in *Gen-Probe*, had not established an actual controversy. Pet. App. 37a. The District Court further stated that it found the conclusions of the Federal Circuit "compelling" and "controlling." Pet. App. 38a.

C. The Federal Circuit's Affirmance

The Federal Circuit affirmed the District Court's dismissal. The court reviewed the nature of the Declaratory Judgment Act and Article III and explained that "[t]o keep watch over the subtle line between an 'abstract question' and 'a controversy contemplated by the Declaratory Judgment Act,' . . . an inquiry has been formulated that focuses on the conduct of both the patentee and the accused infringer." Pet. App. 4a-5a. The court further explained that "[w]hen a potential infringer seeks declaratory relief in the absence of a lawsuit by the patentee, there must be both (1) a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity." Pet. App. 5a.

The Federal Circuit reviewed its *Gen-Probe* decision and agreed with the district court that *Gen-Probe* was determinative. The court then held that the Sublicense

Agreement eliminated any pre-license controversy alleged by MedImmune:

> Any controversy that may have existed between MedImmune and Centocor prior to and during their various negotiations vanished when MedImmune executed the license agreement, which is a covenant by Centocor not to sue. Quite simply, once the license agreement was in place and MedImmune was in compliance with the terms of the agreement, MedImmune could not be under a reasonable apprehension that it would face an infringement suit by Centocor.

Pet. App. 5a-6a.

The Federal Circuit rejected MedImmune's arguments that the *Gen-Probe* decision was inconsistent with precedent of this Court, specifically *Cardinal Chemical Co. v. Morton Int'l*, 508 U.S. 83 (1993) and *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), explaining that neither case concerned the issue of patent declaratory judgment jurisdiction. Pet. App. 6a-8a. The Federal Circuit similarly disagreed with MedImmune's argument that the *Gen-Probe* decision was inconsistent with the Federal Circuit's own precedent.[3] Pet. App. 8a-9a. The court also rejected MedImmune's argument that Respondents' suit against MedImmune *after* the filing of MedImmune's declaratory judgment suit altered the analysis, stating "[t]he presence or absence of a case or controversy is based on facts at the time the complaint was filed." Pet. App. 9a (citing *GAF Bldg Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 483 (Fed. Cir. 1996)).

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[3] The Federal Circuit further rejected MedImmune's assertion that the Sublicense Agreement permitted this suit because it did not contain an agreement not to litigate. The court stated that "[t]his assertion overlooks the fact that a license is, by its nature, an agreement not to litigate." Pet. App. 6a n.1.

Petitioner filed a petition for rehearing and rehearing *en banc*, which the Federal Circuit unanimously denied. Pet. App. 40a.

REASONS FOR DENYING THE PETITION

Petitioner MedImmune seeks review by this Court in order to change the "actual controversy" standard for patent cases brought under the Declaratory Judgment Act. MedImmune's Petition presents the specific question of whether a licensee (in this case a sublicensee) may challenge a licensed patent while the licensee continues to make royalty payments to ensure that it retains all of the benefits of its license. The Federal Circuit correctly decided that there is no case or controversy over such a suit. Far from being a change in the law, that decision, and the Federal Circuit's earlier decision in *Gen-Probe*, are consistent with long-standing Federal Circuit law, firmly grounded in this Court's precedent, and compatible with case law from the other circuit courts.

The decisions below and in *Gen-Probe* were correct. MedImmune's petition ignores the simple fact that the Sublicense Agreement resolved any disputes that the parties may have had regarding the '715 Patent. The parties to the Sublicense Agreement are performing, and no disputes have arisen other than MedImmune's unilateral decision to challenge the licensed patent on the same grounds it raised when it sought to drive down the royalty rate during the license negotiations. There is thus no immediate controversy at this time as MedImmune faces no possible threat of infringement litigation and merely seeks to subvert the purpose of the Sublicense Agreement into which it voluntarily entered.

MedImmune incorrectly asserts that "the *Gen-Probe* doctrine" effectively eliminated declaratory judgment suits by patent licensees against their licensors in contravention of *Lear v. Adkins*, 395 U.S. 653 (1969). *See* Pet. at 8. In *Lear*, the license agreement was breached and there was no reason

for this Court to consider the question of whether a patent licensee may file suit *while maintaining the benefits of its license*. Here, Respondents gave up their right to sue MedImmune and obtain the full range of remedies provided under the patent laws by entering into the Sublicense Agreement and agreeing to a negotiated royalty rate. Correspondingly, MedImmune obtained protection from any suit in exchange for the payment of agreed upon royalties. Yet, MedImmune would force Respondents to defend themselves in this litigation in contravention of their own contractual covenants and with Respondents having no ability to recover their full measure of damages. Prohibiting Respondents from exercising these rights while simultaneously permitting MedImmune to litigate would create an inequitable imbalance in the licensing system that was never contemplated by *Lear*. Thus, and as explained more fully below, Respondents respectfully request that the writ be denied.

I. THE FEDERAL CIRCUIT'S *GEN-PROBE* DECISION IS NOT A CHANGE IN THE LAW

MedImmune contends that the Federal Circuit's *Gen-Probe* decision, upon which dismissal below was based, sets a "new" and "arbitrary" standard for determining declaratory judgment jurisdiction. *See* Pet. at 12. To the contrary, the *Gen-Probe* court merely applied the two-part test that the Federal Circuit has used for more than twenty years in determining whether a case or controversy exists in patent actions. *See Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1331 (Fed. Cir. 2005); *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996); *Spectronics Corp. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991); *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 862 (Fed. Cir. 1987); *Jervis B. Webb Co. v. S. Sys., Inc.*, 742 F.2d 1388, 1398 (Fed. Cir. 1984).

The two-part test is firmly rooted in this Court's precedent. Indeed, the Federal Circuit has repeatedly relied upon this Court's statements in *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) that the presence of an "actual controversy" within the meaning of the Declaratory Judgment Act depends on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient *immediacy* and reality to warrant the issuance of a declaratory judgment." *See, e.g., Teva*, 395 F.3d at 1331; *Gen-Probe*, 359 F.3d at 1379-80. In the patent context, the Federal Circuit looks to the conduct of both parties (thus the two-part test) to determine whether there is an immediate patent infringement controversy. *Teva*, 395 F.3d at 1332; *Gen-Probe*, 359 F.3d at 1380.[4]

MedImmune has objected to the application of the two-part test to a declaratory judgment plaintiff who is a licensee in good standing. However, it was neither new nor arbitrary for the Federal Circuit to apply its declaratory judgment standard to a patent licensee. In *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874 (Fed. Cir. 1983), the Federal Circuit applied a "reasonable apprehension of an infringement suit" test to a licensee-plaintiff to determine whether a case or controversy existed over its declaratory judgment action for invalidity of the licensed patent while the patent license was in effect. *Id.* at 879-81. Because the licensee-plaintiff in *Bard* (unlike MedImmune here) had stopped paying royalties, the Federal Circuit determined that the plaintiff faced a real risk of suit, which satisfied the requirements for a declaratory judgment action. In another Federal Circuit decision, the court stated:

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[4] The two-part test is: (1) a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity. *See, e.g., Teva*, 395 F.3d at 1331.

"a licensee . . . cannot invoke the protection of the Lear doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid." *Studiengesellschaft Kohle, m.b.H. v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir. 1997).

II. THE FEDERAL CIRCUIT'S DECISION BELOW AND IN *GEN-PROBE* WERE CORRECT

The decisions below, and the earlier *Gen-Probe* decision, were correct. In *Gen-Probe,* the Federal Circuit carefully considered the competing interests of licensors and licensees to confirm that the two-part test applies in the patent license context. 359 F.3d at 1382. As the court explained, licensors would unjustly bear all of the risks of a licensee's challenge if the licensee were permitted to bring a suit challenging a licensed patent without giving up the protection of its license. *Id.*

The Federal Circuit's rationale is compelling. There is a contractual parity that provides an incentive for parties to enter into license agreements and share technology. By granting the license, the licensor, at a minimum, gives up the ability to enforce the patent at a time and in an appropriate forum of its choosing, and to recover damages in excess of the compromised royalty rate, potentially enhanced damages for willful infringement, and an injunction. The licensee is immune from these risks by virtue of being licensed and in exchange for the payment of royalties.

Before *Lear*, licensee estoppel disrupted this parity and provided licensors with considerable power over their licensees where, after entering into a license agreement, the licensee concluded that a licensed patent was invalid or unenforceable. Pre-*Lear,* the licensee faced a no-win situation: if it stopped making royalty payments, it would not be allowed to defend itself in a subsequent breach of contract

action by asserting that such patent was invalid or unenforceable. *Lear* abolished the doctrine of licensee estoppel in such circumstances to eliminate this inequity.

MedImmune seeks to swing the pendulum too far in the opposite direction, placing too much power into the hands of a licensee who wants to challenge a licensed patent at the expense of the licensor. Indeed, the licensor would stand to lose its right to continue receiving royalty payments, have to pay for the very litigation it contracted to avoid, and have no chance of any recovery other than that to which it was already contractually entitled. The licensee, on the other hand, would risk nothing by a challenge to the licensed patent other than its litigation fees. Even if the challenge failed, the licensee would continue to enjoy the same immunities and benefits under the license agreement at the same royalty rate.

If MedImmune's position were accepted, a licensee would be permitted to challenge a licensed patent essentially *whenever* it wanted without giving up any benefits under the license. This result would be at odds with the "immediacy" requirement for a constitutional case or controversy, as jurisdiction could be established at any time. *See Maryland Cas.*, 312 U.S. at 273. In addition to greatly enlarged patent jurisdiction, licensors would also be forced to live in continued fear of suit from their licensees, a result contrary to the very purpose of the Declaratory Judgment Act. *See Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-735 (Fed. Cir. 1988). Licensees, on the other hand, would be encouraged to enter into agreements to insulate their risk and gain the benefit of licensed technology and then evade the equities of those agreements by forcing licensors to defend against patent challenges without a full range of remedies.[5]

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[5] Such a result would discourage licensing, which fosters competition by making technology and intellectual property more widely available.

The decisions in *Gen-Probe* and this case thus strike the appropriate balance of power between the licensor and licensee. A party may challenge a patent that it has licensed as in *Lear*, but it cannot do so while maintaining and enjoying its rights under the license. Indeed, as the Federal Circuit below explained, every potential infringer "must decide to settle or fight." Pet. App. 10a. MedImmune's attempt to afford itself the ability to do both is fundamentally unfair to licensors.

III. THIS CASE INVOLVES PATENT AND NOT CONTRACT JURISDICTION

MedImmune argues that *Gen-Probe* conflicts with contract declaratory judgment case law and policy, particularly *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). In citing contract case law, MedImmune neglects the fact that, to the extent that there is a controversy here, it is grounded in patent rather than general commercial law. Indeed, the issues MedImmune sought to litigate are purely patent in nature: invalidity, noninfringement and unenforceability.[6] These are the very same issues that MedImmune raised and could have sought to litigate *instead of* signing the Sublicense Agreement.

Alternatively, the only way prospective licensors could ensure themselves of the benefit of their bargain would be by filing suit first and then entering into a license agreement as part of a consent decree or settlement agreement. The licensor would thereby obtain *res judicata* of the licensees' patent claims. *See Foster v. Hallco Mfg. Co.*, 947 F.2d 469 (Fed. Cir. 1991). Encouraging licensors to file suit when they are considering granting a license would have the undesired effect of overburdening the federal court system and slowing down the licensing cycle, thereby creating unnecessary delays in taking products to market.

[6] MedImmune's "Question Presented" confirms that the underlying action is patent in nature. Moreover, in order to avoid arbitration, MedImmune argued successfully before the District Court that this action was a patent dispute, not a contract dispute. CAA. 513, 536.

By contrast, a true contract dispute is one that has *arisen from* the contract itself and would not exist independently. These cases generally involve the application of the parties' agreement to circumstances arising *after* execution of the contract. *See e.g., Aetna*, 300 U.S. at 237-38; *Keener Oil & Gas Co. v. Consol. Gas Utilities Corp.*, 190 F.2d 985, 989 (10th Cir. 1951); *Am. Machine Metals Inc. v. De Bothezat Impeller Co.*, 166 F.2d 535, 536 (2d Cir. 1948). Unlike those cases, MedImmune is not seeking to interpret a contractual provision or to resolve a good faith dispute that has arisen from the contract. Instead, the only dispute here is the one that MedImmune unilaterally created by raising the same challenges to the '715 patent that it asserted *before* signing the Sublicense Agreement.

Moreover, there is a fundamental difference between patent litigation involving parties to a license agreement and general contract declaratory judgment actions. As explained above, a patent license by its very nature is a covenant not to sue based on the licensed patent in exchange for a compromised royalty rate. *See* Pet. App. 6a n.1. Thus, through the present type of action, a patent licensee would not only undermine its license agreement, it would do so in a manner that strikes at the very heart of the consideration for the agreement. Such a challenge would place the licensor in a uniquely unfair position—the licensor loses its contractual benefits of foregoing litigation and stands to lose the negotiated royalties but has no ability to seek the full measure of damages to which it would have been entitled had it not entered into the license agreement. There is no analogous issue in the contract cases relied upon by MedImmune as general contracts typically do not include a covenant not to sue as part of the bargained-for consideration.

As this Court has explained, Congress created the Court of Appeals for the Federal Circuit to increase uniformity in patent-related decisions. *See Markman v. Westview Instr. Inc.*, 517 U.S. 370, 390 (1996). The Federal Circuit has been

consistent in its application of an "actual controversy" standard in patent cases. *See supra* Section I. MedImmune has not presented any compelling reason to upset the settled expectations of litigants and deviate from long-standing Federal Circuit law in favor of some other standard derived from contract declaratory judgment case rulings that have no sensible application to this case.

IV. THE FEDERAL CIRCUIT'S DECISION DOES NOT CONFLICT WITH THE DECISIONS OF THIS COURT OR OTHER COURTS OF APPEAL

A. Precedent Of This Court

The case law relied upon by MedImmune does not establish a conflict in the law. MedImmune argues that *Gen-Probe* is "irreconcilable" with this Court's decision in *Lear*, 395 U.S. 653 (1969). Specifically, MedImmune suggests that *Lear* permits its present action, but that the Federal Circuit has eroded *Lear* over time, effectively eliminating it with the *Gen-Probe* holding. *See* Pet. at 18-19. The *Gen-Probe* and *Lear* decisions, however, present no conflict. *Lear* originated as a state court breach of contract action filed by the licensor after the licensee had stopped paying royalties under a license agreement. 395 U.S. at 659-60. The Court held that, as a matter of public policy, the licensee was not estopped from asserting patent invalidity as a defense in the breach of contract action. *Id.* at 673-74. *Lear* never addressed the question presented in *Gen-Probe* of whether there is a case or controversy over a licensee's challenge to a licensed patent while the licensee is maintaining the protection of its license.[7]

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[7] MedImmune cites *Diamond Scientific Co. v. Ambico, Inc.*, 848 F.2d 1224 (Fed. Cir.), *pet'n for cert. dismissed*, 487 U.S. 1265 (1988) and *Kohle*, 112 F.3d at 1561, to support its contention that "*Lear* has been under attack for years" in the Federal Circuit. *See* Pet. at 19. While both of those cases involved facts different from those in *Lear*, the Federal Circuit nevertheless carefully considered the principles of *Lear* and

Like the licensee in *Lear*, MedImmune is free to challenge the licensed patent and nothing in *Gen-Probe* prevents it from making the choice to stop making royalty payments and assert such a challenge.

MedImmune also relies on *Altvater v. Freeman*, 319 U.S. 359 (1943) in attempting to establish that *Gen-Probe* conflicts with decisions of this Court. In *Altvater*, this Court expressly stated that it was *not* considering the question of whether a licensee—*i.e.*, a party who *voluntarily* pays for the use of a licensed patent—can challenge the validity of the patent. *See id.* at 364. Indeed, the Court stated, "[w]e can put to one side . . . [whether] a *licensee* is estopped to challenge the validity of a patent . . . " *Id.* Of significance to the *Altvater* Court's opinion was the fact that the lower courts had determined that the license agreement had been terminated and that plaintiff was involuntarily paying royalties "under the compulsion of an injunction decree" from an earlier litigation involving a patent that had been surrendered to the Patent Office in a reissue proceeding. *Id.* at 365. Thus, *Alvater* is readily distinguishable on its facts.

MedImmune further argues that *Gen-Probe* conflicts with *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). As explained above, *Aetna* does not address declaratory

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followed *Lear*'s approach of weighing the equities to determine whether federal patent policies would be "significantly frustrated" by enforcing contractual covenants. *See Diamond*, 848 F.2d at 1224 (holding that the assignor-inventor was estopped from defending against an infringement action by challenging the validity of the patents it assigned because "[t]o allow the assignor to make that representation [of the worth of the patent] at the time of the assignment (to his advantage) and later to repudiate it (again to his advantage) could work an injustice against the assignee . . ."); *Kohle*, 112 F.3d at 1568 (holding that the lower court could enforce a license for the period of time before the licensee's challenge to the validity of the licensed patent because of the licensee's delay in timely challenging the patent to the detriment of the public). Thus, the Federal Circuit has not undermined this Court's decision in *Lear*.

judgment jurisdiction over a patent action. Other facts in *Aetna* also clearly distinguish it from *Gen-Probe* and the present case. In *Aetna*, the insured had stopped making premium payments on the grounds that his disability relieved him of such obligation. 300 U.S. at 239, 242. The insurance company disagreed that the insured was disabled and sought declaratory judgment that four policies had lapsed due to non-payment and that the company had no obligation to provide certain benefits. *Id.* The Court indicated that the insured could have brought suit at any point demanding benefits. *Id.* at 243. This case does not present a comparable fact pattern: at no point after the Sublicense Agreement was signed could respondents have sued MedImmune. The *Aetna* case is not "even remotely similar or analogous" to the circumstances present in *Gen-Probe* or this case. 359 F.3d at 1382.

B. Decisions From Other Circuit Courts

MedImmune attempts to establish a conflict among the circuit courts, arguing that the *Gen-Probe* decision is "not logically limited to patent licenses" and "affects basic federal law through the country." *See* Pet. at 10. This argument ignores the fundamental point that *Gen-Probe* considered whether a case or controversy existed in a *patent* dispute. As explained above, there is a significant difference between a *patent* declaratory judgment action between parties to a license agreement and a non–patent *contract* declaratory judgment action. Regardless, a review of the case law cited by MedImmune demonstrates that there is no conflict between the Federal Circuit's application of the two-part declaratory judgment standard and decisions of other circuit courts.

MedImmune quotes *Sallen v. Corinthians Liceniamentos LTDA*, 273 F.3d 14 (1st Cir. 2001), to support its contention that other circuits have recognized that an Article III case or controversy may be established in the absence of "apprehension of a lawsuit." In *Sallen*, however, the court merely determined that application of the "reasonable apprehension

of suit" test was not necessary because the domain name dispute "had already *progressed far beyond* . . . cases in which a declaratory defendant only questionably threatened suit." *Id.* at 26 (emphasis added). Indeed, the plaintiff had already been brought before a World Intellectual Property Organization ("WIPO") panel, lost the use of its domain name through WIPO dispute resolution proceedings, and was seeking through its declaratory action to overturn the decision of the WIPO proceeding. *Id.* The court specifically contrasted these facts with cases where the controversy surrounds a potential, future lawsuit, for which the court indicated the "reasonable apprehension of suit" test would govern. *Id.* at 25. Thus, far from establishing a split among circuit courts, this case is consistent with Federal Circuit law.

MedImmune also argues that the *Gen-Probe* line of cases "cannot be reconciled with the law applied to licenses of intellectual property in other circuits." Pet. at 17 (citing *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1556 n. 23 (9th Cir. 1990); *Société de Conditionnement v. Hunter Engineering Co.*, 655 F.2d 938, 943-44 (9th Cir. 1981)). Neither case involved the issue presented in *Gen-Probe*. *Hal Roach* involved a suit by a copyright owner/licensor—and not a licensee—seeking a declaration that the license agreement would expire on a certain date and that the licensor had valid copyrights. 896 F.2d at 1544-45. The licensee, among other things, raised copyright invalidity as an affirmative defense. *Id.* at 1553. Thus, the facts are very different from the present case.

MedImmune's reliance on *Société* is also misplaced. Contrary to MedImmune's argument, *Société* did not concern a declaratory judgment action between parties to a patent license or any other type of contract. *See* Pet. at 17. Instead, the plaintiff filed suit against a competitor after the competitor's technical director threatened a mutual customer with patent litigation to deter the customer from purchasing

additional products from the plaintiff, and the customer requested an indemnity. 655 F.2d at 940-41. Although *Société* was decided before the creation of the Federal Circuit, the case or controversy standard that the court applied (whether "the plaintiff has a real and reasonable apprehension that it will be subject to liability if he continues to manufacture his product") is not significantly different from the Federal Circuit's two-part test. *See id.* at 944. Thus, this case also presents no conflict with Federal Circuit law.

MedImmune argues that *Gen-Probe* is incompatible "with federal law on declaratory actions involving licenses and other contracts generally." Pet. at 17-18 (citing *Keener Oil & Gas Co. v. Consol. Gas Utilities Corp.*, 190 F.2d 985, 989 (10th Cir. 1951); *Am. Machine Metals Inc. v. De Bothezat Impeller Co.*, 166 F.2d 535, 536 (2d Cir. 1948)). As explained in section III above, those cases are inapplicable because they involve contractual disputes arising from the agreements at issue.[8]

V. THE DECISION BELOW RESTS ON SOUND PUBLIC POLICY

MedImmune's final argument focuses on risk, and asserts, incorrectly, that the Federal Circuit decision in this case and other cases following *Gen-Probe* somehow put licensees at a disadvantage in challenging patents they believe to be invalid or unenforceable.

License agreements, by their nature, are risk management tools. In order to avoid the risks inherent in litigation over a patent and a potentially infringing product, the parties agree on a licensing arrangement and negotiate a royalty rate commensurate with their respective risk assessments. That is

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[8] MedImmune further cites to decisions pre-dating the creation of the Federal Circuit. The Federal Circuit has resolved any conflict presented in those decisions.

how the licensing system works in the United States and neither *Gen-Probe* nor the decision below will change that. Rather, these cases promote licensing, by encouraging established companies to grant licenses to newer, younger businesses, knowing that they can rest assured that the license agreement will provide a safe haven for them to share technology in an agreed-upon, negotiated setting.

MedImmune wants to change this negotiated equipoise so that all of the risk is borne by the licensor, leaving the licensee free to challenge the patent at a moment's notice, without losing the safety net of the license agreement. MedImmune describes its position as a way of "restor[ing] the balance enacted by Congress in the patent laws." *See* Pet. at 22. In fact, MedImmune seeks to skew the balance entirely in favor of licensees, thereby throwing into disarray the settled expectations of parties who participate in the license system, and in all likelihood, discouraging patent holders from entering into license agreements with start-up companies with unproven track records in terms of their willingness to honor and abide by a negotiated license and not file suit.

MedImmune also argues that the holding of *Gen-Probe* is particularly unjust to smaller/startup companies, characterizing itself as such a company that was threatened and forced by a big company to pay royalties or else risk losing its business. This characterization is unfounded as explained above. *See supra* n.2. MedImmune is a sophisticated company that exercised its business judgment to enter the Sublicense Agreement only after a lengthy period of negotiation, during which MedImmune received advice and opinions from at least two law firms and asserted a number of invalidity and non-infringement arguments to negotiate down the proposed royalty rate. MedImmune does not need or warrant special protection from the Court, especially protection that runs contrary to the legal and public policy reasons discussed above.

CONCLUSION

For all of the foregoing reasons, the Court should deny MedImmune's petition for writ of certiorari.

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(3)

No. 05-656

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,
Petitioner,

v.

CENTOCOR, INC., *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY TO BRIEF IN OPPOSITION

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IN THE

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REPLY TO BRIEF IN OPPOSITION

The Brief in Opposition argues at length that the Federal Circuit's application of Article III is consistent with some of its own earlier cases, and that as a matter of patent policy it is desirable. Br. Opp. 8-15, 19-20. Neither argument goes to the issue presented by the petition. That issue is whether the Federal Circuit has put itself in conflict with the understanding of Article III and the Declaratory Judgment Act applied in other Circuits, as well as with this Court's holdings, on a key provision defining the federal judicial power.

1. The Brief in Opposition seeks to minimize many of the Declaratory Judgment Act cases from other Circuits as "contract cases," which it proposes to segregate from "patent cases" involving license contracts. Br. Opp. 13-15. Why a

supposed jurisdictional requirement of Article III and the Declaratory Judgment Act, demanding a prior material breach of a contract, would apply only to patent-license contracts, respondents do not explain. The Brief in Opposition also disregards *en masse* the clearly conflicting decisions on Article III rendered when the regional Circuits had patent jurisdiction. See Pet. Cert. 15-16; Br. Opp. 19 n.8.

2. Respondents argue that the Federal Circuit's recent *Gen-Probe*[1] line of decisions, of which this is one, is nothing new in that Circuit. Br. Opp. 8-11. That is demonstrably incorrect.[2] Indeed, the District Court so recognized when it changed its initial jurisdictional ruling 180° because *Gen-Probe* in the interval had been decided. *Compare* P.C.A. 20a *with id.* 37a-38a. But even if the recent *Gen-Probe* line of cases were not new, that would be no less reason to grant certiorari to resolve that Circuit's now-firmly-established divergent understanding of Article III.

3. Respondents fail to escape this Court's fundamental decisions going back to the 1930s which laid down juris-

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[1] *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 543 U.S. 941 (2004), followed in *Metabolite Labs., Inc.* v. *Laboratory Corp.*, 370 F.3d 1354, 1369 (Fed. Cir. 2004), *cert. granted on another question*, 126 S. Ct. 601 (2005); in *Teva Pharmaceuticals USA, Inc.* v. *Pfizer, Inc.*, 395 F.3d 1324 (non-license case), *rehearing en banc denied*, 405 F.3d 990 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005); in *MedImmune, Inc.* v. *Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005), *pet'n for cert. pending* (No. 05-608); and in the present case.

[2] See, *e.g.*, *C.R. Bard, Inc.* v. *Schwartz*, 716 F.2d 874, 882 (Fed. Cir. 1983) ("We hold that a patent licensee may bring a federal declaratory judgment action . . . without prior termination of the license."); *Gen-Probe Inc.* v. *Vysis, Inc.*, No. 99-CV-2868H (S.D. Cal. Mar. 12, 2002) ("It is settled law that an effective license between the parties does not preclude federal question jurisdiction over a licensee's declaratory judgment action."), *rev'd*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 543 U.S. 941 (2004) (reprinted in Petition for Certiorari, *Gen-Probe Inc.* v. *Vysis, Inc.*, No. 04-260, at 25a).

dictional principles the Federal Circuit has abandoned. In *Altvater* v. *Freeman*, 319 U.S. 359 (1943), a patent-license declaratory-judgment case, the licensee, as here, was paying royalties; that the license contract had been enforced by an injunction did not affect the applicable principle. This Court was explicit that "certainly the requirements of case or controversy are met where payment of a claim is demanded as of right and where payment is made," and "[t]he fact that royalties were being paid did not make this a 'difference or dispute of a hypothetical or abstract character.'" *Id.* at 364, 365, quoting in part *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 240 (1937). The Declaratory Judgment Act, this Court long ago held, requires simply a legal dispute that is "definite and concrete, not hypothetical or abstract." *Aetna*, 300 U.S. at 242.

4. The District Court explicitly ruled that "[a]lthough the parties are under license, there is a clear and concrete dispute between them . . . ." P.C.A. 18a-19a.[3] *Cf. Altvater*, 319 U.S. at 364 ("A controversy was raging, even apart from the continued existence of the license agreement."). Indeed, respondents themselves earlier had alleged that a case or controversy was present when they sought a federal declaratory judgment based on the same facts in California.[4] The District

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[3] Petitioner's complaint alleged in detail that it had been threatened with suit repeatedly by Centocor; Centocor had asserted that MedImmune's Synagis® infringed the patent, and warned that it had a policy of bringing suits against infringers. C.A.A. 455-57. MedImmune had responded that the patent was invalid and not infringed, and that in these circumstances there was no obligation to pay royalties; Centocor explicitly disagreed. C.A.A. 459-60. The only fact the courts below held controlling was that petitioner had not stopped paying royalties under the license. P.C.A. 5a-6a, 37a-38a.

[4] That California federal action was dismissed, not because of the license, as respondents mistakenly imply, Br. Opp. 5, but rather because of this earlier-filed federal action in Maryland. See P.C.A. 14a: "The Universities have misstated the rationale that the [California] Court used

Court in Maryland dismissed in obedience to the jurisdictional requirement imposed by the Federal Circuit in *GenProbe* requiring that there must be a prior material breach of the license. P.C.A. 37a-38a.

5. The Brief in Opposition argues that "[a] party may challenge a patent that it has licensed . . . but it cannot do so while maintaining and enjoying its rights under the license." Br. Opp. 13. But this Court in *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969), pointedly rejected "[t]he theory . . . that a licensee should not be permitted to enjoy the benefit afforded by the agreement while simultaneously urging that the patent which forms the basis of the agreement is void." *Id.* at 656. This Court acknowledged that a licensee might "avoid[] the necessity of defending an expensive infringement action during the period when he may be least able to afford one," *id.* at 669, but did not accept the argument that therefore the licensee should be prevented from challenging the licensed patent, *id.* at 669-74.

Respondents nevertheless complain that for petitioner as licensee to challenge the patent is unfair to the licensor. Br. Opp. 12-13, 20. But as the Second Circuit explained, that policy judgment was settled in *Lear*:

> "A licensee who wishes to continue using the patented element cannot withhold royalty payments without laying himself open to large potential liability for infringement and an injunction against all future use of the patented substance. If forced to make the hard choice, many licensees will choose the less perilous course, and the patents under which they are licensed will remain uncontested. *Lear* established that removing restraints on commerce caused by improperly-held patents should

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in finding there to be no 'actual controversy'. . . . It did not do so . . . because of the license between the parties. Rather, the Court found that the likelihood of an infringement suit was low because of the Maryland action . . . ."

> be considered more important than enforcing promises between contracting parties. Thus, the seeming inequity of allowing a licensee to keep his license while he attacks the validity of the licensor's patent is outweighed by the public interest in placing no impediment in the way of those in the best position to contest the validity of the underlying patent."

Warner-Jenkinson Co. v. *Allied Chem. Corp.*, 567 F.2d 184, 187-88 (2d Cir. 1977). Any equities favoring the licensor, the Court in *Lear* concluded, "[s]urely . . . do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." 395 U.S. at 670.

"Licensees may often be the only individuals with enough economic incentive to challenge" a licensed patent, and "[i]f they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification." *Id.* at 670. Contrary to the policy arguments respondents urge, this Court decided that the unmuzzling of licensees to challenge invalid patents served the public interest, "particularly . . . in the many scientific fields in which invention is proceeding at a rapid rate," *id.* at 673, so that "the technical requirements of contract doctrine must give way before the demands of the public interest." *Id.* at 670. See also *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993) ("importance to the public at large of resolving questions of patent validity"). And even if *Lear* were believed bad policy after all,[5] the solution would not be what

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[5] The Federal Circuit several times has expressed its hostility to the federal patent policy recognized in *Lear*. *E.g.*, *Studiengesellschaft Kohle, m.b.H.* v. *Shell Oil Co.*, 112 F.3d 1561, 1567 (Fed. Cir.) (calling *Lear* an "echo from a past era of skepticism over intellectual property principles"), *cert. denied*, 522 U.S. 966 (1997); *Diamond Scientific Co.* v. *Ambico, Inc.*, 848 F.2d 1220, 1224-25 (Fed. Cir.) (rejecting patent challenge "despite

the Federal Circuit chose here: an unauthorized and unprecedented contortion of Article III of the Constitution.[6]

6. Respondents observe that the Court of Appeals—for the Federal Circuit was created to provide expertise and consistency in patent-related decisions. Br. Opp. 14. But the Federal Circuit was not created to devise interpretations of the Declaratory Judgment Act and Article III that conflict with those of the other Circuits and this Court.

CONCLUSION

For the reasons stated herein and in the petition, certiorari should be granted.

Respectfully submitted,

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January 12, 2006

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the public policy" of *Lear*), *pet'n for cert. dismissed*, 487 U.S. 1265 (1988).

[6] See also *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d at 964, reiterating that "[t]he court in *Gen-Probe* discussed the inequity" of suits by licensees not in material default, holding that "[t]his imbalance distorts the equalizing principles that underlie the Declaratory Judgment Act."